89-2430

No. _____

In The Supreme Court of the United States October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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QUESTION PRESENTED

35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

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v.

MEDTRONIC, INC.,

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The petitioner Eli Lilly and Company ("Lilly") respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989.[1] The question presented is purely a legal one. Because the Court of Appeals' decision is so clearly erroneous, this case is appropriate for summary reversal pursuant to Rule 23.1 of the Rules of this Court.

[1] Pursuant to Rule 28.1 of the Rules of this Court, Lilly states that it has no publicly owned parents, subsidiaries, or affiliates.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 872 F.2d 402, and is reprinted in the appendix ("Pet. App.") hereto, page 1a. The Court of Appeals denied a timely petition for panel rehearing on May 31, 1989 (Pet. App. 8a), and issued its judgment as a mandate on June 8, 1989 (Pet. App. 14a). The Court of Appeals declined Lilly's suggestion for rehearing in banc on July 18, 1989 (Pet. App. 9a).[2]

The memorandum decision of the United States District Court for the Eastern District of Pennsylvania rejecting 35 U.S.C. § 271(e)(1) as a defense to patent infringement for medical devices is reported at 5 U.S.P.Q. 2d 1760 (Pet. App. 15a). The district court issued a memorandum decision, 7 U.S.P.Q. 2d 1439, supporting the issuance of a permanent injunction against respondent (Pet. App. 21a). The district court further issued a memorandum decision, 7 U.S.P.Q. 2d 1447, directing that judgment be entered in favor of Lilly (Pet. App. 41a).

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the Court of Appeals was invoked pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1).

The decision of the Court of Appeals was entered on March 29, 1989 (Pet. App. 1a). A timely petition for rehearing was denied on May 31, 1989 (Pet. App. 8a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

35 U.S.C. § 271(e)(1) provides as follows:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The full text of 35 U.S.C. § 271(e) is set forth in petitioner's appendix, pp. 62a-63a.

[2] This Court (White, Justice) denied Lilly's application to stay the mandate of the Court of Appeals on July 24, 1989. *See* Docket No. A-62.

STATEMENT OF THE CASE

Lilly holds the rights to the two patents in suit, which cover an automatic implantable cardioverter defibrillator and associated electrical leads.[3] This medical device treats life-threatening heart arrhythmias in patients who are at high risk of sudden cardiac arrest. The defibrillator dramatically improves the prognosis for persons who have suffered an episode of sudden cardiac arrest: patients with the device have a one-year survival rate of 95-98 percent, compared to 30-60 percent for those without it (Pet. App. 23a-24a).

Pursuant to 28 U.S.C. § 1338(a), Intec Systems, Inc. ("Intec") brought this suit in 1983 in the United States District Court for

[3] The automatic implantable cardioverter system functions like a miniaturized emergency room which may be implanted in the body of the patient. It automatically monitors the heart and shocks the heart back to its normal rhythm when conditions of ventricular tachycardia (abnormally fast heartbeat) or ventricular fibrillation (fluttering of the heart muscles) occur.

The inventor and his initial investor, Intec Systems, Inc., a small Pittsburgh-baced company, toiled for ten years from the time of the invention until the first human implant in 1980 of a commercial embodiment of the patented invention. It took another five years, until 1985, before the Food and Drug Administration approved the patented product for commercial use. In 1985, Lilly paid the developers of the inventions in suit in excess of $60 million plus additional royalties for the exclusive rights to the patented inventions and other assets. Lilly immediately sublicensed its exclusive implantable cardioverter defibrillator patent rights to its wholly owned subsidiary, Cardiac Pacemakers, Inc. ("CPI"). CPI, but not Lilly, makes, uses, and sells automatic implantable cardioverter defibrillators.

the Eastern District of Pennsylvania against respondent Medtronic, Inc. ("Medtronic"). After purchasing certain of Intec's assets in 1985, Lilly was substituted for Intec as the plaintiff. The complaint alleged that Medtronic's development and marketing of its devices infringed the two patents. Plaintiff sought damages and injunctive relief.

In 1987, Medtronic raised a pretrial defense that it made and sold the infringing devices for the purpose of obtaining FDA marketing approval, and that 35 U.S.C. § 271(e)(1) immunized this activity.[4] Section 271(e)(1) was enacted in 1984 and provided then as follows:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.[5]

The district court ruled that this section is limited to drugs and does not provide an exemption for infringing medical devices (Pet. App. 15a). The court reasoned that the statute "clearly speaks" solely in terms of drugs, and the legislative history "evinces the narrow purpose of Congress" to establish a limited exemption for the testing of generic drugs (Pet. App. 18a-19a). "Nowhere," the district court concluded, "is there any indication that Congress had a broader intention to include medical devices within the coverage of § 271(e)(1)" (*id.*).

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[4] Although this lawsuit was initiated in 1983, Medtronic did not raise the Section 271(e)(1) defense until 1987, after Medtronic lost the reexamination proceedings on the patents in suit before the United States Patent and Trademark Office, and nearly two and one-half years after enactment of Section 271(e)(1).

[5] Section 271(e)(1) was amended in 1988 to include certain animal products. Pub. L. No. 100-670, 102 Stat. 3971 (Nov. 16, 1988). The Court of Appeals stated that the amendment did not affect its analysis (Pet. App. 4a). As shown below, however, the amendment confirms the correctness of the district court's and Lilly's interpretation of the statute.

Following a jury trial, the court granted a directed verdict in Lilly's favor with respect to infringement of one patent, and the jury returned a verdict in Lilly's favor with respect to infringement of the other patent, including a jury finding that Medtronic willfully infringed both patents in suit (Pet. App. 22a, 35a). The district court further determined that the patents were valid and enforceable, and it directed that judgment be entered in Lilly's favor in the amount of $26,666,000 (Pet. App. 41a-42a, 55a). The court also entered a permanent injunction against Medtronic's infringement of the Lilly patents (Pet. App. 22a, 40a).

On appeal from the injunction pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1), the Court of Appeals reversed and remanded (Pet. App. 1a). The Court of Appeals concluded that Lilly and Medtronic had "put forth equally plausible interpretations of section 271(e)(1)," and it found both the language and legislative history of the statute to be ambiguous (Pet. App. 5a). The court ruled in Medtronic's favor, however, on the basis of an argument that it developed *sua sponte*.

In the Court of Appeals' view, Section 271(e)(1) should be interpreted by reference not to its language, but to Congress' intent to overrule a prior case involving infringement of a drug patent, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). The Court of Appeals claimed there was a congressional intent to overrule *Bolar* "in all of its ramifications" (Pet. App. 7a), i.e., with respect to numerous other products, including medical devices, food additives, and color additives.

Lilly timely sought rehearing and rehearing in banc. Because of the importance of the court's holding, numerous *amicus* briefs were submitted by manufacturers of medical devices and other FDA-regulated products, as well as by Senator Hatch, the principal author of Section 271(e)(1), and Representative Moorhead, a floor manager for the legislation, supporting Lilly's petition. The Panel, however, denied rehearing without opinion on May 31, 1989 (Pet. App. 8a).

On July 18, 1989, the Court of Appeals declined Lilly's suggestion for rehearing in banc (Pet. App. 9a). Judge Newman dissented on the grounds of the "exceptional importance" of the

case and "the weight of the panel's error" in departing from the clear statutory language (Pet. App. 10a, 13a). Judge Newman indicated that the Panel erroneously "held that the statutory words 'drugs and veterinary biological products' include medical devices." (Pet. App. 10a). Judge Newman further stated:

> The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest. Lilly, and *amici* on its behalf, observe that there are different considerations in connection with medical devices, as compared with human and animal drugs. Congress would be expected to consider the public and private economic and policy aspects of these complex industries. I cannot imagine how, on the record before us, a panel of this court can decide how Congress will decide the issue. *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) ("It is not the function of the courts to amend statutes under the guise of 'statutory interpretation' ").

(Pet. App. 12a-13a) (footnote omitted).

REASONS FOR GRANTING THE WRIT

I. Certiorari Is Necessary to Correct the Court of Appeals' Clear Error on a Matter of National Importance

This is not an ordinary patent case. It involves the construction of a federal statute that will have, unless reversed, a significant negative impact on investment in health-care research and development and on the pace of innovation in lifesaving medical devices. Congress enacted Section 271(e)(1) as part of the most substantial overhaul of the federal food and drug laws in more than twenty years. This statute does not raise any issue within the particular competence of the Federal Circuit. To the contrary, it requires only traditional tools of statutory construction. It also involves an understanding of FDA regulatory processes that is not a routine part of that court's jurisprudence. Moreover, because all appeals concerning patent matters and Section 271(e)(1) are within the exclusive appellate jurisdiction

of the Federal Circuit pursuant to 28 U.S.C. § 1295, the structure of the medical device industry will be changed irretrievably in a manner never anticipated by Congress if this Court does not grant certiorari now.

This Court should grant certiorari for several persuasive reasons discussed in detail below. As Judge Newman stated in her dissent from the denial of the suggestion for rehearing in banc, this case raises a federal statutory issue of "exceptional importance" (Pet. App. 10a, 13a). The decision below ignores the plain language of Section 271(e)(1), notwithstanding the "clarity of [its] words" (*id.* at 13a). By doing so, the Court of Appeals "has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest" (*id.* at 12a).

This Court has granted certiorari in cases decided by the Federal Circuit when important statutory issues were raised, and Congress clearly intended that such access to this Court would be available. *See, e.g., Cornelius v. Nutt*, 472 U.S. 648, 657 (1985); H.R. Rep. No. 312, 97th Cong., 1st Sess. 18-19 (1981). The Court of Appeals' egregious error and the substantial adverse effect of that error on the public health make this case appropriate for review by this Court.

The need for review is confirmed by the substantial judicial disagreement over the interpretation of Section 271(e)(1). Judge Newman dissented sharply from the denial of Lilly's suggestion for rehearing in banc (Pet. App. 10a). Prior to the Court of Appeals' decision, the district court in the instant case, as well as the only other district court to have considered the issue, concluded that Section 271(e)(1) is limited to drugs. *See* Pet. App. at 19a ("the § 271(e)(1) defense [is] inapplicable to medical devices"); *Scripps Clinic & Research Foundation v. Baxter-Travenol Laboratories, Inc.*, 7 U.S.P.Q. 2d 1562, 1565 (D. Del. 1988) ("It is also clear that Section 271(e)(1) applies only to drugs, not to medical devices." (dictum)).

Medical devices are subject to premarket approval and other regulation by the Food and Drug Administration ("FDA"). Prior to the Court of Appeals' decision in this case, it would have been an act of patent infringement to make, use, or sell an infringing

product in studies conducted to obtain the data necessary for FDA commercial approval for medical devices or other nondrug products. The Court of Appeals interpreted a narrow statutory exemption, which universally had been understood to apply *only* to the limited testing necessary for generic drug approvals, to encompass studies for *all* FDA-regulated products.

The Court of Appeals' decision constitutes impermissible judicial legislation. The decision substantially erodes patent protection for inventions pertaining to medical devices, food and color additives, and other FDA-regulated, nondrug products. *See* pages 18-20, *infra*. Under the Court of Appeals' interpretation of Section 271(e)(1), infringers are granted immunity prior to market approval to make, use, or sell these otherwise infringing products without a license from or payment of compensation to the patent holder.

II. The Court of Appeals' Decision Is Directly Contrary to the Statutory Language, Legislative History and Policy of Congress

A. Statutory Language

As recently amended to apply to certain animal drugs and biological products as well as to human drugs, 35 U.S.C. § 271(e)(1) reads as follows:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products* (emphasis added).

The ordinary meaning of the statutory language is that it applies only to "drugs" and "veterinary biological products." "Medical

devices" are not mentioned. Indeed, they are expressly excluded from the definition of "drug" under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). *See* 21 U.S.C. § 321(g)(1) ("The term 'drug' . . . does not include devices or their components, parts, or accessories."). Drugs and devices are regulated under entirely different statutory provisions. *Compare* 21 U.S.C. § 355 (drugs) *with* 21 U.S.C. § 360 (devices).

This should have been the end of the matter.[6] *See, e.g., United States v. James*, 478 U.S. 597, 604-606 (1986). Straining to find an ambiguity, however, the Court of Appeals concluded that the "law which regulates" drugs or veterinary biological products meant the entire FD&C Act, including the device provisions, as well as the Act of March 4, 1913 (under which veterinary biological products are regulated). This reading is directly refuted by the plain language of the statute: a few lines earlier in Section 271(e)(1), Congress referred expressly to the "Federal Food, Drug, and Cosmetic Act" and the "Act of March 4, 1913." It is implausible, to say the least, that Congress then would have used entirely different language to describe the same statutes later in the same provision.

If Congress had intended to provide an infringement exemption for devices as well as for drugs, it would have referred to a law which regulates "drugs *and* devices." Whenever Congress limited or proposed to limit a patentee's rights under Section 271(e)(1), Congress spoke clearly. Congress used clear language to identify "drugs" under the Section 271(e)(1) exemption in the 1984 original enactment. Congress' 1988 amendment of the statute extended the exemption to certain animal drugs and veterinary biological products: Congress did so by adding the express reference to "veterinary biological products" to the end

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[6] Although the Court of Appeals did not accept the argument, Medtronic urged below that the statutory language was ambiguous because Congress referred to a patented "invention" rather than to a patented "drug." The latter term, however, could have limited the provision to product patents and excluded process patents, which Congress intended to cover. Congress therefore used the term "invention" to ensure that all types of drug patents would be included, so long as the claimed invention was used solely for purposes relating to the development of information necessary to obtain drug approval.

of Section 271(e)(1) and deleting the express exclusion for certain "animal drugs" from the "drug" category. See Pub. L. No. 100-670, § 201(*i*)(1), 102 Stat. 3971, 3988 (Nov. 16, 1988).[7]

When Congress enacted the 1984 law, it included protections—by specifying acts of infringement and establishing remedies–for "drug" patent holders under certain circumstances in Sections 271(e)(2) and (e)(4) (Pet. App. 62a-63a). Congress added similar protections for owners of patented animal products in the 1988 amendment to Section 271(e)(1) (*id.*). Had Congress believed that "medical devices" were within the infringement exemption of Section 271(e)(1) as originally enacted, surely Congress would have provided corresponding protections for medical device patent holders in the original enactment of Sections 271(e)(2) and (e)(4). For example, proposed Senate Bill S.622 would add "medical devices" to Sections 271(e)(2) and (e)(4) (Pet. App. 60a-61a). However, the current Sections 271(e)(2) and (e)(4) are specific to "drugs" and "veterinary biological products" and further confirm that their companion Section 271(e)(1) should be construed likewise.[8]

The Court of Appeals' decision inserts the words "medical devices" into Section 271(e)(1) without providing the additional patent protections of Sections 271(e)(2) and (e)(4). This is the worst possible result for medical device patent holders and clearly not intended by Congress.

The Court of Appeals' error is all the more apparent because its reading is not limited to devices. It applies also to every other article regulated under the FD&C Act, such as food additives,

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[7] As further confirmation, a bill pending in Congress at the time of the Court of Appeals' decision, if passed, would have amended the statute by adding the term "medical devices" to the end of Section 271(e)(1). *See* S. 622, 101st Cong., 1st Sess., 135 Cong. Rec. S2860-61 (daily ed. Mar. 16, 1989) (Pet. App. 60a-61a).

[8] The district court held that "other sections of the [Drug Price Competition and Patent Term Restoration Act of 1984] distinguish between 'drugs' and 'devices', further indicating that when Congress intended to include devices within the coverage of a section, it clearly specified as much, rather than assume the term 'drugs' to include 'devices' " (Pet. App. 18a).

color additives, and other substances–none of which is referred to anywhere in Section 271(e)(1). In short, the Court of Appeals expanded a statute that by its terms allowed only a narrow infringement exemption for two specifically mentioned products—drugs and veterinary biological products–to apply to medical devices and other products not mentioned anywhere in the statute itself.[9]

As Judge Newman concluded, the Court of Appeals' departure from the statutory language constitutes impermissible judicial legislation (Pet. App. 12a). *See, e.g., United States v. Rutherford,* 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy."); *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456, (1984), ("it is not our job to apply laws that have not yet been written"); *United States v. Great Northern Ry. Co.,* 343 U.S. 562, 575 (1952) ("It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written.").

B. Legislative History

The legislative history further demonstrates that Congress intended that Section 271(e)(1) would allow infringement only for drugs (and later for animal products), but not for any other FDA-regulated product. There is not a single reference in any legislative history of this provision suggesting the possibility that it would permit infringement of medical device patents.

Two committee reports were prepared on the 1984 legislation that originally enacted Section 271(e)(1): one by the House Committee on Energy and Commerce and one by the House

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[9] The Court of Appeals' reliance on *United States v. Fausto*, 484 U.S. 439 (1988) (Pet. App. 6a), does not support its departure from the statutory language. Rather, that case confirms the importance of both the language chosen by Congress and the congressional intent. The instant case does not raise any question requiring the reconciliation of interrelated laws enacted at different times. Rather, it requires only a straightforward exercise in the interpretation of Section 271(e)(1) based on its plain language and legislative history.

Committee on the Judiciary. H.R. Rep. No. 857, 98th Cong., 2d Sess. Parts 1 and 2 (1984), *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647. Both reports establish that Section 271(e)(1) is directed solely to drugs. *See, e.g., id.*, Part 1, at 15 ("it is not an act of patent infringement for a *generic drug* maker to import or to test a *patented drug* in preparation for seeking FDA approval" (emphasis added)); *id.*, Part 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval of *the drug*." (emphasis added)); *id.* ("The purpose of Section 271(e)(1) and (2) is to establish that experimentation with *a patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." (emphasis added)); *id.*, Part 2, at 27 n.18 (it would not be an infringement to use patented information "for the purpose of obtaining FDA premarketing approval of *a drug*" (emphasis added)); *id.*, Part 2, at 29 (provision "permit[s] the limited testing of *drugs* while they are on patent" (emphasis added)). Similarly, the legislative history of the amendment expanding the exemption to animal products describes Section 271(e)(1) as a provision that "applies to *human pharmaceuticals*." S. Rep. No. 448, 99th Cong., 2d Sess. 13 (1986) (emphasis added).[10]

The Court of Appeals inexplicably dismissed these clear expressions of congressional intent as merely "general statements . . . which allegedly support" the district court's and Lilly's interpretation of the statute (Pet. App. 5a). At the same time,

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[10] Commentators on the 1984 legislation agreed that this provision "is limited to human drug products, and does not include medical devices. . . food additives, color additives, or other related activities." Flannery & Hutt, "Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984," 40 Food Drug Cosm. LJ. 269, 307 (1985); *accord*, Fox & Bennett, "The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984," at 178, 187 (Food and Drug Law Inst. 1987). Similarly, in their *amicus* brief supporting rehearing in the Court of Appeals, the principal Senate author of the 1984 legislation and a primary floor manager in the House stated that section 271(e)(1) was intended to permit only "use of a patented drug product, prior to the patent's expiration, for purposes relating to obtaining FDA approval." Brief of Senator Hatch and Representative Moorhead, at 1.

its opinion (*id.*) gives the erroneous impression, without citation, that there are contrary statements supporting the extension of Section 271(e)(1) to devices. There are none. *See* Pet. App. 5a-7a.

The Court of Appeals concluded *sua sponte*, however, that Section 271(e)(1) was intended to overrule the *Bolar* case, *supra*, "in all of its ramifications" (*id.* at 7a) and thereby to immunize infringement for medical devices and other products not mentioned in the statute itself, in its legislative history, or in the *Bolar* case. This interpretation defies understanding.

Congress intended that Section 271(e)(1) would "have the net effect of reversing the *holding*" in *Bolar*. H.R. Rep. No. 857, *supra*, Part 2, at 27 (emphasis added). Congress understood the court in that case to have "held that the experimental use of a *drug product* prior to the expiration date of a patent claiming that *drug product* constitutes patent infringement." *Id.*, Part 1, at 45-46 (emphasis added); *accord, id.*, Part 2, at 27 n.18. In *Bolar* itself, the Court of Appeals stated that the issue was a "narrow" one:

> does the limited use of a *patented drug* for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

733 F.2d at 861 (emphasis added). Whatever the Court of Appeals now believes its holding to have been, surely it is Congress' understanding at the time it enacted Section 271(e)(1) that is relevant.[11] Thus, Congress overruled *Bolar* "in that (Section 271(e)(1)) would provide that generic *drug* manufacturers can start playing around with the *drug* on which the patent is about to

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[11] "The meaning and effect of legislation whose operation is conditioned by common-law principles *are not changed by subsequent judicial decisions* modifying the common-law principles." 2a *Sutherland Statutory Construction* § 50.02, at 431 (4th ed. 1984) (emphasis added). *See generally, e.g., Mackey v. Lanier Collection Agency & Service, Inc.*, ___ U.S. ___, 108 S.Ct. 2182, 2191 (1988) (" 'It is the intent of Congress that enacted [the section] . . . that controls.' ") (citations omitted).

expire." 130 Cong. Rec. H8712 (daily ed. Aug. 8, 1984) (statement of Rep. Kindness) (emphasis added).

It is difficult to imagine how Congress could have made its intentions any more clearly known. There is simply no basis for concluding that Congress intended anything more than to overrule the precise holding of *Bolar* as Congress and the *Bolar* court understood it, i.e., to prohibit the experimental use of patented drugs for FDA approval purposes. The Court of Appeals here pointed to no evidence of congressional intent, and there is none, suggesting a desire to overrule *Bolar* "in all of its ramifications." The court's *ipse dixit* thus entirely ignores the plainly expressed intention of Congress.[12]

C. Policy and Constitutional Considerations

The application of Section 271(e)(1) only to drugs, which is compelled by its language and legislative history, is further supported by important distinctions between FDA regulation of drugs and medical devices. While the Court of Appeals claimed to discern "[n]o persuasive reason . . . why Congress would create an exception with respect to those activities for drugs only" (Pet. App. 7a), there are in fact sound policy considerations favoring this interpretation. The court apparently failed to appreciate these reasons because it lacked a sufficient understanding of the very different FD&C Act provisions and FDA regulations that govern testing and approval of drugs versus medical devices. *See* Judge Newman's dissenting opinion, Pet. App. 12a ("there are different considerations in connection with medical devices, as compared with human and animal drugs"). The extension of the infringement exemption to medical devices is unsupported as a matter

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[12] Moreover, if Congress intended to overrule all of the "ramifications" of *Bolar*, this would eliminate the experimental-use exception to patent infringement for all inventions, not just for those pertaining to FDA-regulated products. Congress of course intended no such thing, and not even the Court of Appeals suggests that it did. Yet the court offered no justification for picking and choosing among the various "ramifications" of *Bolar* that purportedly were overruled by Section 271(e)(1). The only interpretation that can be defended on the basis of the statutory language and legislative history is that Congress intended to overrule *Bolar* as it applied to drugs.

of sound policy and serves only to retard the development of innovative health products.

New drugs are subject to premarket approval by FDA upon a showing of safety and effectiveness. *See* 21 U.S.C. § 355. Prior to 1984, generic copies of previously-approved drugs generally required their own approvals resting on their manufacturers' own clinical studies. *See United States v. Generix Drug Corp.*, 460 U.S. 453 (1983). The same statute that enacted Section 271(e)(1) also established an "abbreviated" procedure for approval of generic drugs. *See* 21 U.S.C. § 355(j). Under this procedure, a generic applicant is not required to submit independent proof of safety and effectiveness, but need show only that its product is "bioequivalent" to the previously-approved drug–i.e., that it has the same "rate and extent of absorption" into the blood-stream. 21 U.S.C. § 355(j)(7)(B)(i).

Section 271(e)(1) permits such bioequivalence testing prior to the expiration of a drug patent. This testing is conducted in a limited number of volunteers who typically are healthy persons who do not even have the disease for which the drug is intended. These persons are not charged for the drug. Congress found that the "nature of the interference" with a drug patent holder's rights entailed by such bioequivalence testing "is *de minimis*." H.R. Rep. No. 857, Part 2, at 30.[13]

The interference with a medical device patent holder's rights, however, would be far more significant. There is no "abbreviated" procedure for approval of medical devices subject to premarket approval application requirements. See 21 U.S.C. § 360. The medical device testing that would be permitted under the Court of Appeals' decision therefore encompasses full-scale clinical trials rather than the much more limited bioequivalence testing necessary for generic drug approval.

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[13] While the statute also would permit clinical trials of patented drugs, Congress understood that, as a practical matter, manufacturers would take advantage of the much faster and less expensive "abbreviated" procedures which require only bioequivalence testing, rather than undertaking their own clinical tests in hundreds or thousands of patients. *See* H.R. Rep. No. 857, Part 2, at 8.

These clinical trials permit device manufacturers to introduce their products to the market by treating patients with the underlying disease and by involving leading physicians and medical institutions in the studies. Many devices, such as the implantable defibrillators at issue here, are permanently implanted and thus each patient who is treated with the investigational device is unavailable as a customer to the patent holder. Similarly, many devices, such as diagnostic machines, have only a small number of potential customers. Hospitals, for example, may need only one CAT-scan machine, and thus each hospital using an infringing device, even for "investigational" purposes, is lost to the patent holder's market.

Moreover, manufacturers charge for investigational devices, even those that infringe patents. *See* 21 C.F.R. § 812.7(b). Such charges are common for expensive devices such as implantable defibrillators. Medtronic, for example, sold its infringing units for $17,000 each. (Pet.App. 12a n.4). Some medical devices may carry even higher per-item prices. Indeed, a single medical device may itself be sold for a quarter of a million dollars or more. Clinical trials by infringers could rob patent holders of millions of dollars in lost sales, while the infringers themselves recover all of their "costs of manufacture, research, development, and handling" (21 C.F.R. § 812.7(b))–all before the life of the patent has expired.

Accordingly, there are persuasive, solid reasons–rooted in the different testing procedures and approval requirements of drugs and devices–for distinguishing between them in Section 271(e)(1). Those differences raise a serious constitutional question under the takings clause of the Fifth Amendment of the U.S. Constitution if the statute is interpreted to authorize the infringing use of medical devices. *Cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). Section 271(e)(1), as interpreted by the Court of Appeals, impermissibly takes a portion of the exclusive patent rights from medical device patent holders *after* a patent holder has disclosed its invention to the public. Such public disclosure is the *quid pro quo* for the *exclusive patent right* for the *entire* patent term. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, ___ U.S. ___, 109 S.Ct. 971, 977, (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging

the creation and disclosure of new, useful, and nonobvious advances in technology in return for the exclusive right to practice the invention for a period of years.").

When it enacted Section 271(e)(1), Congress addressed this takings question as it applied to drugs, and it concluded that the statute was constitutional largely because of the "*de minimis* economic impact" on patent holders:

> [T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. * * * Thus, the nature of the interference with the rights of the patent holder is not substantial.

H.R. Rep. No. 857, Part 2, at 8; *see also id.*, Part 2, at 27-30; *id.*, Part 1, at 46. The much more substantial economic impact of an infringement exemption for medical devices raises a correspondingly more substantial constitutional issue. That issue would be avoided, as it should be, by interpreting Section 271(e)(1) in accordance with its plain meaning and legislative history to apply only to drugs and veterinary biological products. *See generally Ashwander v. TVA*, 297 U.S. 288, 346-348 (1936) (Brandeis, J., concurring).

Finally, the Court of Appeals' decision will have a significant deleterious effect on medical device innovation, and therefore on the public health. The patent system is intended to provide the necessary incentive for "inventiveness and research efforts." *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980). That incentive would be seriously eroded if infringement is immunized for device testing purposes. *See* pages 18-20, *infra*.

At the same time that it enacted Section 271(e)(1), Congress provided for the partial extension of drug and device patents in order to "create a significant, new incentive which would result in increased expenditures for research and development" in the health-care industry. H.R. Rep. No. 857, *supra*, Part 1, at 18. While Congress was willing, as part of a compromise with generic drug interests, to make a *de minimis* exception for drug bioequivalence testing, it did not make the much larger inroad on

patent rights that a device exception would represent.[14] Such an exception would eviscerate the very research incentives that Congress had intended to expand in the 1984 legislation. As Judge Newman concluded, "[t]he panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest." (Pet. App. 12a).

For all these reasons, the Court of Appeals seriously erred in departing from the plain language, legislative history and policy underpinnings of Section 271(e)(1).

III. An Exceptionally Important Federal Statutory Issue Is Before This Court

This case raises a federal statutory issue of exceptional national importance (Pet. App. 10a, 13a). The Court of Appeals determined that infringing medical devices undergoing clinical trials prior to patent expiration are entitled to a limited non-infringement defense under Section 271(e)(1).

Millions of dollars of medical devices undergoing clinical trials are sold in the United States each year. For example,

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[14] Contrary to arguments presented by Medtronic below, there is no indication in the legislative history that Section 271(e) (1) was intended to apply to devices as a *quid pro quo* for extension of device patent terms under 35 U.S.C. § 156(b), as enacted by the 1984 legislation. Section 271 (e) (1) and Section 156(b) are not, and were never intended to be, parallel in scope. For example, Section 271 (e) (1) is applicable to many patents that do not meet the numerous eligibility requirements for extension under Section 156(b). *Cf. Fisons v. Quigg*, 876 F.2d 99 (Fed. Cir. 1989) (discussing eligibility restrictions). Additionally, the Section 271(e) (1) exemption applies at any time during the life of a patent and does *not apply solely* during the extended period of a patent provided by Section 156(h).

The Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (1984), that enacted Section 271(e)(1) plainly was a compromise between opposing innovator pharmaceutical companies and generic drug interests. *See, e.g.*, 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore); *id.* at H8706-07 (daily ed. Aug. 8, 1984) (statements of Reps. Kastenmeier and Waxman). There is no indication that device manufacturers had any part in the legislative compromise or were granted any special exemption by Congress in the legislation.

Medtronic sells its infringing devices for $17,000 per unit *during clinical trials* (Pet.App. 12a n.4). Medtronic projected its cumulative revenue from the sale of infringing devices manufactured in the United States through its fiscal year of 1990 in the amount of $11 million–all, according to Medtronic, during clinical trials (*id.*). Other competitors also would be encouraged to enter into or continue similar clinical trials based upon the Court of Appeals' decision. Thus, the total pre-expiration sales of infringing devices (and direct loss of sales to Lilly's subsidiary, CPI) using the basic patent in this suit could be several times the amount projected by Medtronic. Under the guise of "research" or "experimentation," competitors could erode twenty-five percent or more of Lilly's market–prior to the expiration of the patents in suit–in the name of "clinical testing."

This example, of course, relates to just one patent in a particular medical device field. With the development of medical devices in the broad areas of heart-assist devices, lung and kidney devices, and the literally unlimited number of other medical devices, the decision of the Court of Appeals takes on great public significance in the medical device field alone. For expensive, long-lasting devices for which the number of potential customers is relatively small, the sale of such devices during the investigational period (for example, the sale of CAT-scanners, x-ray and ultrasound machines, and other diagnostic machines to hospitals) may erode substantially the market for a patented device even prior to FDA approval.

The Court of Appeals' decision will discourage precisely what the patent laws are intended to encourage–innovation, technological development, and investment in high-risk ventures, such as the automatic implantable cardioverter defibrillator. The Court of Appeals' decision will encourage copying instead. The decision will also increase federal patent litigation by encouraging infringement, and by spawning numerous and complex disputes over whether particular activities come within the exemption of Section 271(e)(1).

The investment community will view medical device patents as high-risk properties of doubtful value. Money needed to develop promising inventions will be diverted away from pioneering inventors and directed to copiers and infringers after the inventor

and his investors have taken the risk to establish the success of the invention. On the day of the Court of Appeals' decision, Medtronic's stock "soared 4-1/2 to 87-1/2 before trading was halted later in the session. . . ." *Wall Street Journal,* March 30, 1989, p. C2.

In a technology-driven industry, such as the field of automatic implantable defibrillators and other high-technology medical devices, a company's technical reputation benefits all of its product lines. Medtronic recognized the importance of technological reputation by proclaiming itself the "technological leaders in the tachy arena" after only the first clinical-trial implant of its infringing defibrillator (Trial Ex. 143). The ripple effect of this reputation, which can be secured during clinical trials by courting key opinion leaders, is to: (1) open customer doors previously closed for other products; (2) attract new research talent and leadership; and (3) obtain access to the *limited* number of clinical sites, key physician investigators, and suitable patients for clinical trials (Hauser Trial Test., Day 16, pp. 20-21; Luceri Trial Test., Day 4, pp. 139-40). The Court of Appeals' decision deprives medical device patent holders of these benefits afforded a patent owner for its *exclusive* patent rights.[15]

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[15] By losing its exclusive patent position and the benefits arising from the exclusive patent rights, Lilly is being irreparably harmed. The district court concluded that, without an injunction, Medtronic would use "its current strength in the pacemaker industry to dominate the market involving devices for treating tachycardia and fibrillation" (Pet. App. 37a). The district court found that Lilly "will be irreparably harmed if Medtronic is not enjoined from further infringement of Lilly's patents" (*id.*).

CONCLUSION

The Court of Appeals' decision is erroneous. Congress has not enacted the law that the Court of Appeals has legislated. Injustice has resulted to patent holders for FDA-regulated medical devices and other nondrug products, to the long-term detriment of the public health.

For the foregoing reasons, this petition for certiorari should be granted. Because the Court of Appeals' decision is so clearly erroneous, summary reversal is appropriate.

Respectfully submitted,

Dated: August 10, 1989

/s/ TIMOTHY J. MALLOY

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APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

DECIDED: March 29, 1989

Before NIES, *Circuit Judge,* COWEN, *Senior Circuit Judge,* and ARCHER, *Circuit Judge.*

NIES, *Circuit Judge.*

Medtronic, Inc., brings an interlocutory appeal from a permanent injunction[1] entered by the United States District Court for the Eastern District of Pennsylvania, *Eli Lilly & Co. v. Medtronic, Inc.,* No. 83-5393 (E.D. Pa. Apr. 21, 1988) (Ditter, J.), enjoining it from, *inter alia,* the manufacture, use, or sale of certain medical devices, and from the use of data generated from such medical devices. Medtronic asserts that 35 U.S.C. § 271(e)(1) (Supp. III 1985) permits the use it is making of its medical devices, namely, for testing and obtaining certain approval by the Food and Drug Administration (FDA). Prior to trial, the district court had ruled that that statute applies to drug products only; Medtronic could not, therefore, assert it as a defense against Lilly's charges of infringement. *See Eli Lilly & Co. v. Medtronic, Inc.,* 5 USPQ2d 1760 (E.D. Pa. 1987). We disagree. Accordingly, we reverse the court's ruling that 35 U.S.C. § 271(e)(1) is restricted to drugs, and we remand for determination of whether, in fact, Medtronic's use of its medical devices falls under section 271(e)(1). Because it is unclear that all of Medtronic's activities fall within

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[1] This court has jurisdiction over this appeal pursuant to 28 U.S.C. §§ 1292 (a) (1) and (c) (1) (1982).

the section 271(e)(1) exception, we leave it for the court on remand to decide to what extent the injunction should be vacated, modified, or stayed during further proceedings.

I

As an initial matter, we note that the propriety of the grant or denial of an injunction under 35 U.S.C. § 283 (1982) is reviewable under an abuse of discretion standard. *Windsurfing Int'l. v. AMF Inc.*, 782 F.2d 995, 1002, 228 USPQ 562, 567 (Fed. Cir.), *cert. denied*, 477 U.S. 905 (1986). However, abuse of discretion may be established by showing an injunction is based upon a misinterpretation of applicable law. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988) (quoting *PPG Indus. v. Celanese Polymer Specialities Co.*, 840 F.2d 1565, 1572, 6 USPQ2d 1010, 1016 (Fed. Cir. 1988) (Bissell, J., additional views)). Here, we conclude that the district court interpreted 35 U.S.C. § 271(e)(1) too narrowly.

II

BACKGROUND

Lilly sued Medtronic for infringement of claims 1-6 of its U.S. Patent Re. No. 27,757 and claim 1 of U.S. Patent No. 3,942,536 under 35 U.S.C. § 271(a) (1982). Lilly alleged that Medtronic's development and marketing of its automatic implantable cardioverter defibrillators and catheter electrodes infringed Lilly's patents covering such medical devices. Medtronic asserted the statutory noninfringement defense provided by 35 U.S.C. § 271(e)(1), and moved for partial summary judgment on that basis. *See Eli Lilly & Co.*, 5 USPQ2d 1760. The court denied Medtronic's motion, ruled that section 271(e)(1) does not apply to medical devices, and prohibited Medtronic from presenting evidence at trial regarding the section 271(e)(1) defense. *Id.* at 1762. Following a trial on the merits, which resulted in Medtronic being held to infringe Lilly's patents, the district court reaffirmed its interpretation of section 271(e)(1) and issued the subject injunction. *See Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033, 7 USPQ2d 1439 (E.D. Pa. 1988).

III

This case raises a question of first impression, namely, whether the noninfringement defense of 35 U.S.C. § 271(e)(1), added by amendment in 1984, applies to medical devices.

Shortly before section 271(e)(1) was enacted, this court addressed whether it was an infringing use under 35 U.S.C. § 271(a)[2] for a nonlicensee to use a patented drug product, prior to the patent's expiration, for purposes strictly related to obtaining FDA approval for a generic substitute intended to be sold commercially only after the patent expires. The case addressing that issue was *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). This court in *Roche* concluded that such use did not fall within any established experimental use exception and declined to extend or create an experimental use exception for FDA testing. The court noted that Congress was the appropriate forum to resolve the matter and that legislation was pending on related subjects which made it aware of the problem. *Id.* at 865, 221 USPQ at 942. Under the *Roche* ruling, infringement would be found for the investigational testing of an infringing medical device even though, under 21 U.S.C. § 360e (1982 & Supp. III 1985) of the Federal Food, Drug, and Cosmetic Act, such testing is required to obtain FDA approval to market such devices.

The *Roche* decision resulted in an immediate effort by the generic drug manufacturers to escape the effect of the decision. An amendment of the patent statute was put forth in connection with the pending legislation noted in the *Roche* decision.[3] Before Congress, those interests urged that the time required to obtain FDA approval for their generic products, if they had to wait to begin testing until after a patent expired, gave an effective

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[2] Section 271(a) provides: "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

[3] The pending legislation provided for abbreviated testing procedures for generic drugs. H.R. 3605, 98th Cong., 1st Sess. (1983) ("Drug Price Competition Act of 1983").

extension of the patent term, which was contrary to the interests of the public in obtaining lower cost drugs as soon as possible. It was an objective of the generic drug manufacturers to be able to place their generic substitutes for a patented drug on the market the day after the patent expired. That objective could be achieved only if they were able to acquire data and apply to FDA prior to that time, activities which were legally impermissible under *Roche*. At the same time, Congress had before it bills supported by the proprietary drug interests which had as their objective the extension of the patent term. The justification for such extension also lay in the FDA testing requirements which consumed, in many instances, a number of years of the patent term and effectively reduced the patentee's time for exclusive commercial exploitation of the invention.

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the Act), signed into law in 1984, simultaneously effected some of the aforementioned objectives. The Act overruled *Roche* by adding section 271(e)(1) to title 35 which reads[4] in pertinent part:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Section 271(e)(3) (Supp. III 1985) further provides:

> In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

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[4] On November 16, 1988, President Reagan signed Public Law No. 100-670, entitled the "Generic Animal Drug and Patent Term Restoration Act," into law. Although that law amends 35 U.S.C. § 271(e)(1), the amendment does not affect our analysis here.

Conduct within the ambit of section 271(e)(1) is not an act of infringement, and, hence, cannot be enjoined pursuant to section 271(e)(3). This appeal raises the question of whether section 271(e)(1) is a limited exception which applies only to drugs, as the district court ruled, or applies generally to patented inventions, including medical devices.

In the patent term restoration portion of the legislation, which became codified in 35 U.S.C. § 156 (Supp. III 1985), the benefits of patent extension are not restricted to drugs, but extend to medical devices. *See* 35 U.S.C. § 156(f)(1)(B).[5]

IV

Each of the parties has urged that the above-quoted statutory language of 35 U.S.C. § 271(e)(1) is "clear." However, each has put forth equally plausible interpretations of section 271(e)(1), which to us means the language is fraught with ambiguity. The district court and Lilly limit the exception for "patented inventions" to patented *drugs* by reading the last clause of 271(e)(1) as a restriction on that otherwise broad statutory language. Medtronic urges that the exception extends to all types of "patented inventions" provided the use being made is for testing to obtain approval from FDA for sale of a product after the relevant patent has expired. Per Medtronic, the last clause describes the type of law, not the type of patented invention. Furthermore, as is often the case, each side has been able to highlight general statements in the legislative history which allegedly support their own reading of section 271(e)(1). However, amidst ambiguous language in the statute, and ambiguous statements in the legislative history, what is clear to this court, as well as to the parties and the district court, is that section 271(e)(1) was added to overrule this court's decision in *Roche*.

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[5] 35 U.S.C. § 156 (f)(1)(B) defines the word "product" for which the term of a patent may be extended to include:

> Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

While the claimed subject matter in *Roche* was limited to a drug product, the holding of that case was not so limited. The holding provided an interpretation of the scope of 35 U.S.C. § 271(a) without regard to what particular goods might be involved. Specifically, the court decided that the unlicensed use of a patented invention for testing and investigation, even though strictly related to obtaining FDA approval for a substitute, was an infringement under 35 U.S.C. § 271(a). Apart from *Roche*, there is no other precedent directly on the point.

Congress explicitly stated: "The provisions of section 202 of the bill [i.e., the amendment of Title 35 adding section 271(e)(1)] have the net effect of reversing the holding of the court in *Roche*." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 27, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2711. The clear intent of Congress was to create an FDA experimental use exception for use which *Roche* had held would constitute infringement under section 271(a)(1). *Id.*, pt. 1 at 45-46, *reprinted* at 2678-79. The effect of the section 271(e)(1) amendment as a restriction on section 271(a) is comparable to the interrelationship of statutes addressed by Justice Scalia in *United States v. Fausto*, 108 S. Ct. 668 (1988). There he points out that:

> Repeal by implication of an express statutory text is one thing; it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change. . . . But repeal by implication of a legal disposition implied by a statutory text is something else. The courts frequently find Congress to have done this–whenever, in fact, they interpret a statutory text in the light of surrounding texts that happen to have been subsequently enacted. This classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. And that is what we have here.

108 S. Ct. at 676. This is what we have here as well. No statutory language is section 271(a) is repealed by implication. Rather, the *Roche interpretation* of the language of section 271(a) is necessarily repealed (that is, by implication) by the addition of

section 271(e)(1). In overturning *Roche*, Congress eliminated *certain activity* as being infringing. No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation. Further, it simply makes no sense to apply *Roche* as precedent to nondrug products when the case has no precedential value as to the specific products of the *Roche* suit, namely, drugs. We can only conclude that Congress intended the enactment of section 271(e)(1) to set aside the *Roche* interpretation of section 271(a) in all of its ramifications. Accordingly, we hold that section 271(e)(1) allows a party to make, use, or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

Relief

The court indicated, when deciding Medtronic's summary judgment motion regarding the availability of section 271(e)(1) as a defense, that a genuine issue of material fact exists as to whether Medtronic's use of its devices was "*solely* for purposes reasonably related to submission of information" to the FDA. *Eli Lilly & Co.*, 5 USPQ2d at 1761 n.6. Accordingly, we remand this case to the district court for determination of that factual issue. Because we are not certain whether Medtronic's section 271(e)(1) defense, if valid, goes to the entirety of its otherwise infringing activities, we leave it to the district court to decide whether the injunction should be vacated, modified, or stayed while the trial of the above issue is proceeding.

Costs

Each party shall bear its own costs.

REVERSED AND REMANDED

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

Before NIES and ARCHER, *Circuit Judges*, and COWEN, *Senior Circuit Judge*.

ORDER

A petition for rehearing having been filed in this case, a response thereto having been invited by the court and filed, two amicus curiae briefs in support of the petition for rehearing and two amicus curiae briefs in opposition to the petition for rehearing having been filed,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, denied.

The suggestion for rehearing in banc is under consideration. The mandate will issue on June 7, 1989.

FOR THE COURT

/s/ FRANCIS X. GINDHART

FRANCIS X. GINDHART
CLERK

May 31, 1989

cc: PHILIP S. JOHNSON
TIMOTHY J. MALLOY
PAUL DAVID SCHOENLE
CARLOS J. MOORHEAD
ORRIN G. HATCH
MICHAEL I. RACKMAN
GEORGE GERSTMAN

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

CORRECTED ORDER

A suggestion for rehearing in banc having been filed in this case, a response thereto having been invited by the court and filed, and two amicus curiae briefs in support of the suggestion for rehearing in banc and two amicus curiae briefs in opposition to the suggestion for rehearing in banc having been filed,

UPON CONSIDERATION THEREOF, it is

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, declined.

FOR THE COURT

/s/ FRANCIS X. GINDHART

FRANCIS X. GINDHART
CLERK

July 18, 1989

cc: PHILIP S. JOHNSON
TIMOTHY J. MALLOY
PAUL DAVID SCHOENLE
CARLOS J. MOORHEAD
ORRIN G. HATCH
GEORGE GERSTMAN
RONALD L. HEMINGWAY
MICHAEL I. RACKMAN

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

NEWMAN, *Circuit Judge*, dissenting from the denial of rehearing in banc.

In view of the exceptional importance of the matter, Fed. R. App. P. 35, and the weight of the panel's error, I respectfully dissent from the court's denial of rehearing in banc.

The panel, reversing the judgment of the district court, held that the statutory words "drugs or veterinary biological products" include medical devices.

The statute with which the panel was dealing, as enacted in 1984, was explicitly limited to "the manufacture, use, or sale of drugs".[1] The legislative history stated:

> The purpose of Section 271(e)(1) and (2) is to establish that experimentation with *a patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. [emphasis added]

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[1] P.L. 98-417, codified at 35 U.S.C. § 271(e) (1):
It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the *manufacture, use, or sale of drugs*.
(emphasis added) 35 U.S.C. § 271(e) (1) (Supp. II 1984).

H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 45, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2678.

By congressional action in 1988, after hearings, the statute was extended to animal drugs and veterinary biological products.[2] At the time of the panel's decision in March 1989 there was pending legislation to extend the statute to medical devices. Congress had scheduled hearings. On introducing S.622 Senator DeConcini stated:

> The 1984 law was explicit with respect to human drug products and, with the enactment of Public Law 100-670, is now explicit with respect to animal drug products. The law is not explicit with respect to medical devices and this must be clarified.

135 Cong. Rec. S2861 (daily ed. Mar. 16, 1989).

The panel held that the statute already covered medical devices.

The district court had limited the statute to its plain terms, on the multiple grounds of the clear statutory language; the definition in the Food, Drug, and Cosmetic (FFDC) Act of "drugs" as excluding "devices or their component parts or accessories"; the absence of indication in § 271(e)(1) that "drugs" was intended to be interpreted contrary to the FFDC, which Act is referred to in § 271(e)(1); the distinct procedures set in the FFDC for drugs and devices; the clarity with which Congress specified the inclusion of medical devices when such was intended; and the legislative history that refers solely to drugs. *Eli Lilly and Co.*

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[2] P.L. 100-670, the present text of 271 (e) (1):
It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the *manufacture, use, or sale of drugs or veterinary biological products*.
(emphasis added) 35 U.S.C.A. § 271(e) (1) (West Supp. 1989).

v. Medtronic Inc., 5 USPQ2d 1760, 1761-62 (E.D. Pa. 1987).[3]

In *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456, 220 USPQ 665, 684 (1984), the Supreme Court again cautioned the judiciary that

> it is not our job to apply laws that have not yet been written.

The panel stated that it was implementing congressional "intent". It is indeed possible that Congress would have amended the statute to include medical devices. However, the legislation had not yet been enacted. It is for Congress, not the courts, to change the law for policy reasons. *Sony, supra; BankAmerica Corp. v. United States*, 462 U.S. 122, 140 (1983) (the Supreme Court is not to rewrite a statute based on its notions of appropriate policy); *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written").

The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest. Lilly, and *amici* on its behalf, observe that there are different considerations in connection with medical devices, as compared with human and animal drugs.[4] Congress would be expected to consider the public

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[3] Another district court has identically interpreted the statute. *Scripps Clinic and Research Foundation v. Baxter Travenol Laboratories, Inc.*, 7 USPQ2d 1562, 1565 (D. Del. 1988) ("It is also clear that section 271(e)(1) applies only to drugs, not to medical devices.")

[4] It is undisputed that the Medtronic devices (cardioverter defibrillator units) infringe the Lilly patent, that the devices are sold at $17,000 each, that eleven million dollars of infringing sales are projected through 1990, and that this activity began early in the patent life, well before patent expiration. These circumstances, while specific to the case at bar, lend weight to Lilly's position that pre-registration activity for medical devices is significantly different from that for human and animal devices.

I remark on the anomaly whereby sales of unregistered medical devices may now be deemed non-infringing for as long as they are unregistered. This curious outcome would surely have been explored at congressional hearings.

and private economic and policy aspects of these complex industries. I can not imagine how, on the record before us, a panel of this court can decide how Congress will decide the issue. *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) ("It is not the function of the court to amend statutes under the guise of 'statutory interpretation' "); *Hobbs v. McLean*, 117 U.S. 567, 579 (1886) ("When a provision is left out of a statute either by design or mistake of the legislature, the courts have no power to supply it. To do so would be to legislate, and not to construe.") Yet the panel concluded not only that Congress intended to view these industries in exactly the same way, but that this intent was already enacted into law.

This is not a matter of imprecise or ambiguous words. The clarity of the words is unchallenged. Scant respect has been accorded our admonition in *Roche Products, Inc. v. Bolar Pharmaceutical Co.. Inc.*, 733 F.2d 858, 865, 221 USPQ 937, 942 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), wherein this court wrote:

> No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation.

* * *

The Federal Circuit has a role in our judicial system that is unique among the circuits, in that our decisions are of national effect. There rests upon us a special responsibility, for there is no other forum in which litigants may seek a different result. We must be vigilant to our own errors, and receptive to self-correction. Both the principle, and the specific question here raised, are of exceptional importance, and require rehearing by the full court.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA in CASE NO(S). 83-5393.

This CAUSE having been heard and considered, it is ORDERED and ADJUDGED: REVERSED AND REMANDED

ENTERED BY ORDER
OF THE COURT

/s/ FRANCIS X. GINDHART

Mar 29, 1989

FRANCIS X. GINDHART
CLERK

ISSUED AS A MANDATE: June 8, 1989

APPENDIX E

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

MEMORANDUM AND ORDER

DITTER, J. **December 4, 1987**

Plaintiff Eli Lilly & Co. (Lilly)[1] brought this action against defendant Medtronic, Inc. (Medtronic), charging Medtronic with infringement of two of its patents, U.S. Patent Reissue No. 27,257 and U.S. Patent No. 3,942,536, in violation of the U.S. Patent Act, 35 U.S.C. 271(a) (1982).[2] Lilly contends that Medtronic's development and marketing of its automatic implantable cardioverter defibrillators and catheter electrodes has infringed Lilly's patents covering such devices.[3] Medtronic argues, however, that §271(e)(1) of the Patent Act provides it a statutory noninfringement defense to any claim of infringement and has moved

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[1] The original plaintiff in this action was Intec Systems, Inc. After Intec Systems was acquired by Eli Lilly & Co., Lilly was substituted as plaintiff by stipulation of the parties.

[2] 35 U.S.C. §271(a) provides: "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent. 35 U.S.C. §271(a) (1982).

[3] These devices identify and correct ventricular tachyarhythmias. They consist of a defibrillating or cardioverting system which uses a single intravascular catheter electrode to discharge electrical energy into an ailing heart, thereby eliminating the fibrillation of the heart and decreasing cardiac mortality in patients. Plaintiff's Complaint para. 13.

for partial summary judgment on this issue.[4]

Section 271(e)(1) of the Patent Act provides:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

35 U.S.C. §271(e)(1) (Supp. III 1985). In any action for patent infringement, §271(e)(3) further provides that "no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1)." *Id.* §271(e)(3). Activities which fall within the protection of §271(e)(1) are, thus, exempt from any charge of infringement.

Congress enacted §271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Act), Pub. L. No. 98-417, 98 Stat. 1585. As the legislative history indicates, the enactment of the section was in response to the concern within the pharmaceutical industry and the public that the arrival of generic drugs on the market was being delayed since the bioequivalency testing required by the Food and Drug Administration (FDA) of such drugs could not begin until the expiration of the patents covering the patented equivalents of the generic drugs. *See e.g.*, H.R. Rep. No. 98-857, 98th Cong., 2d Sess., *reprinted in* 1984 U.S. Code Cong. & Ad. News 2647, 2678-79, 2692-93. Much of this concern stemmed from the United States Court of Appeals for the Federal Circuit's decision in *Roche*

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[4] The parties agree that the applicability of 271(e)(1) to medical devices is an issue of first impression for this court and for any court in the country. While the district courts in *Eli Lilly & Co. v. Premo Pharmaceutical Laboratories*, No. 78-2589 (D.N.J. March 27, 1987) and *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987) addressed the applicability of §271(e)(1), they did so in the context of human drug products rather than medical devices. Those decisions, thus, are inapplicable to this case.

Products Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (Fed. Cir.) *cert. denied*, 469 U.S. 856 (1984). In *Bolar*, the defendant obtained a patented drug in order to conduct bioequivalency tests of its generic version of the patented drug. The Federal Circuit held this use of the patented drug infringing under the Patent Act, notwithstanding that it was limited to testing and investigation strictly related to FDA approval. *Bolar*, 733 F.2d at 862-63. To prevent this result, §271(e)(1) overruled *Bolar* by providing that use of a patented invention solely for purposes relating to the reporting requirements of federal drug laws is not infringement of a patent, thus allowing the use of a patented drug for bioequivalency testing of a generic drug. The 1984 Act further authorizes an abbreviated new drug application under the Federal Food, Drug, and Cosmetic Act (FFDC Act), 21 U.S.C. §301-392 (1982 & Supp. III 1985), for generic drugs, thereby hastening their introduction into the marketplace.[5]

Medtronic contends that §271(e)(1)'s noninfringement defense prevents Lilly from recovering for infringement of its patents because Medtronic's uses of its allegedly infringing devices occurred solely for purposes reasonably related to its submission of information regarding the devices to the FDA under the FFDC Act. It is Lilly's contention, though, that §271(e)(1), referring as it does to the submission of information under a federal law regulating "drugs" is wholly inapplicable as a defense for the infringing use of devices such as Medtronic's. Since I find that the statutory language of §271(e)(1) and the

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[5] Title II of the Act, which contains §271(e)(1), also restores part of the patent protection lost by new drugs, human biological products, medical devices, and food and color additives as a result of FDA pre-market testing and approval requirements. Under current patent law, a patent continues to run while the maker of the product is testing and awaiting approval by the FDA to market it. Because of the FDA testing and approval requirements, the effective life of the patent and the protection it gives the patentee from infringement of his product is often much less than the 17 years provided under the patent law. *See* Flannery and Hutt, Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984, 40 Food Drug Cosm. L.J. 269, 301 (1985). To recoup some of the protection-time lost by patentees to the FDA requirements, the Act provides for extension of a patent term of up to 5 years. *See* 35 U.S.C. §156 (Supp. III 1985).

legislative history of the section support Lilly's contention that §271(e)(1) is inapplicable to medical devices, I will deny Medtronic's motion for partial summary judgment.[6]

The statutory language of §271(e)(1) clearly speaks in terms of the submission of information under a federal law regulating "drugs". Medtronic's invitation to construe the term "drugs" to include federal laws regulating both drugs or devices must be rejected. The FFDC Act itself defines "drugs" as excluding devices or their component parts or accessories. 21 U.S.C. §321(g)(1) (1982). While the FFDC Act undoubtedly is a federal law which by its terms regulates both drugs and devices, there is no indication in the statutory language of §271(e)(1) that the phrase "Federal law which regulates . . . drugs" was meant to include anything but drugs as they are defined by the FFDC Act, and not both "drugs" and "devices". Moreover, within the FFDC Act itself, separate and distinct procedures apply with regard to the manufacture, use, and sale of drugs and the manufacture, use, and sale of devices. *See, e.g.*, 21 U.S.C. §355(b) and (j) (1982 and Supp. III 1985) (application for approval of new drugs); 21 U.S.C. §360j(g) (1982) (exemption for devices for investigational use). Finally, other sections of the 1984 Act distinguish between "drugs" and "devices", further indicating that when Congress intended to include devices within the coverage of a section, it clearly specified as much, rather than assume the term "drugs" to include "devices".[7]

More compelling, perhaps, than the statutory language of §271(e)(1), however, is the legislative history of the section itself.

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[6] Even were I to hold §271(e) (1) applicable to medical devices, a genuine issue of material fact exists as to whether Medtronic's use of its devices was *solely* for purposes reasonably related to submission of information under the federal drug laws, thereby precluding summary judgment on this issue. *See Scripps Clinic and Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987)

[7] For example, the patent extension section of the 1984 Act extends the patent life for inventions covering certain "products." "Products" are then defined to include a human drug product or any medical device, food additive or color additive. 35 U.S.C. §156 (f)(1) (Supp. III 1985).

Repeatedly the House report[8] indicates that the specific purpose of §271(e)(1) was to overrule the *Bolar* decision and allow the bioequivalency testing of generic drugs without fear by manufacturers of patent infringement. Emphasizing the limited nature of the exemption, the House Report states that the purpose of §271(e)(1) "is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 98-857, 98th Cong., 2d Sess., *reprinted* in 1984 U.S. Code Cong. & Ad. News 2647, 2678. Nowhere in the legislative history is there any indication that Congress had a broader intention to include medical devices within the coverage of §271(e)(1). Rather, the legislative history evinces the narrow purpose of Congress to advance the quickened entry of generic drugs onto the market through unhampered bioequivalency testing. Similar testing, it is worthwhile to note, is not required of medical devices.[9]

Medtronic argues, finally, that §271(e)(1) is the quid pro quo for the patent extension granted by the 1984 Act. That is, Medtronic contends that in exchange for the grant of patent extension, Congress made available to both manufacturers of drugs and of medical devices the defense of §271(e)(1). There is no support for this contention in either the statutory language of the 1984 Act or its legislative history. Further, were I to accept Medtronic's broad construction of §271(e)(1), I would be removing the very protection which Congress sought to give patentees through the patent extension provision and through the Patent Act generally. Section 271(e)(1), as drafted by Congress, is but a narrowly-drawn exception to this protection.

Having determined the §271(e)(1) defense inapplicable to medical devices, I will, therefore, preclude defendants' presenting evidence at trial in this regard.

An appropriate order follows.

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[8] No Senate or Conference Committee Report on the 1984 Act was issued.

[9] While medical devices are indeed subjected to periods of FDA pre-approval testing, such testing does not involve the comparison of an unpatented device with its patented prototype, as is the case with bioequivalency testing of generic drugs.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

ORDER

AND NOW, this 4th day of December, 1987, for the reasons stated in the accompanying memorandum, it is hereby ordered:

1. Defendant Medtronic, Inc.'s motion for partial summary judgment is denied.

2. The statutory infringement defense of 35 U.S.C. §271(e)(1) does not apply to medical devices.

3. Defendant is precluded from presenting at trial evidence regarding the §271(e)(1) defense.

BY THE COURT:

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APPENDIX F

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,

v.

Civil Action No. 83-5393
Philadelphia, Pennsylvania
Friday, April 15, 1988

MEDTRONIC, INC.,

TRANSCRIPT OF THE COURT'S FINDINGS OF FACT and CONCLUSIONS OF LAW
BEFORE THE HONORABLE J. WILLIAM DITTER, JR.
UNITED STATES DISTRICT COURT JUDGE

APPEARANCES:

COUNSEL FOR PLAINTIFF:
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Philadelphia, Pennsylvania 19103

(Whereupon, the Court began proceedings at 10:40 a.m.)

THE COURT: Good morning, gentlemen.

MR. MALLOY: Good morning.

MR. JOHNSON: Good morning.

THE COURT: The jury returned its verdict in this case on March the 23rd, and on March the 25th, I heard argument concerning whether there was inequitable conduct on the part of the plaintiff and whether plaintiff is entitled to an injunction.

I have concluded that there was no inequitable conduct on the part of the plaintiff and that would be the subject of a separate memorandum which I believe will be issued next week.

I also conclude that the plaintiff is entitled to an injunction and in that regard, I will make findings of fact and conclusions of law on the record at this time. Although I have had the benefit of the transcript in the preparation of these findings of fact and conclusions of law, if it is necessary to do so, I will supplement both the findings of fact and conclusions of law at a later time.

By way of introduction. The plaintiff, Eli Lilly and Company, brought this suit against defendant, Medtronic Incorporated, alleging infringement by Medtronic of two United States patents, No. Re 27,757 re-examined and issued as Bl Re 27,757, which I will refer to as simply the '757 patent, and No. 3,942,536, re-examined and issued as Bl 3,942,536 which I will refer to as the '536 patent.

After a month long trial, I granted Lilly's motion for a directed verdict with regard to the validity of the '536 patent and its infringement by Medtronic.

The jury subsequently returned a verdict in favor of Lilly having found Medtronic's devices to infringe the '757 patent. Lilly has requested an injunctive relief against Medtronic.

In connection with Lilly's motion, I make the following findings of fact:

Plaintiff, Eli Lilly and Company, is a company incorporated in Indiana with its place of business in Indianapolis.

The defendant, Medtronic, Incorporated, is a corporation incorporated in Minnesota with its principal place of business in Minneapolis.

The '757 patent is for a defibrillator which automatically monitors the heart and provides an electrical shock to the heart if ventricular tachycardia or ventricular fibrillation occur. The purpose of the shock is to cause the heart to return to normal, rhythmic beating.

The '536 patent is for the associated intravascular catheter or lead used with the defibrillator to carry the heart-shocking electrical energy from the defibrillator to the heart. The '536 patent provides for at least two heart-shocking electrodes disposed on the same lead, one in a chamber of the heart to be defibrillated and the other outside that chamber.

Dr. Michel Mirowski is the owner of both patents-in-suit.

Lilly is the exclusive licensee of Dr. Mirowski. Lilly has sublicensed its subsidiary Cardiac Pacemakers, Inc., which I will refer to as CPI, to manufacture and sell products embodying the inventions of the patents in suit.

The Food and Drug Administration has approved the use of the devices manufactured by Lilly and CPI under the patents in suit for the treatment of ventricular tachycardia and ventricular fibrillation, two life-threatening arrhythmias, in patients who are at high risk of sudden cardiac arrest.

Ventricular tachycardia is the abnormally rapid beating of the ventricles of the heart.

Ventricular fibrillation is the rapid, disorganized contraction or fluttering of the ventricles of the heart. Ventricular tachycardia frequently leads to ventricular fibrillation if it is not treated.

Since the heart does not pump appreciable amounts of blood during ventricular fibrillation, ventricular fibrillation is always critical and usually fatal unless it is treated.

In the United States alone, up to 450,000 deaths a year are caused by sudden cardiac arrest attributable to ventricular tachycardia or ventricular fibrillation. Those patients who

survive an episode of sudden cardiac arrest have a survival rate ranging from 30 to 60 percent during the first year after that episode.

Conventional drug therapy is often not capable of treating many surviving patients and preventing an episode of sudden cardiac arrest.

Patients who have survived an episode of ventricular tachycardia or ventricular fibrillation and who receive a CPI implantable defibrillator have a survival rate of 95 to 98 percent for the first year after their initial episode.

The device produced by Lilly and CPI under the '757 and '536 patents is an automatic implantable defibrillator and its associated lead.

Medtronic, a leading producer of cardiac pacemakers, and of other medical devices, previously held a license from Dr. Mirowski for the patents-in-suit.

Medtronic returned Dr. Mirowski's patent rights in September, 1972, having decided not to develop Dr. Mirowski's invention on a commercial basis.

In 1979, Medtronic attempted to acquire Dr. Mirowski's patent rights or to reacquire Dr. Mirowski's patent rights, but was unsuccessful.

Medtronic began the first manufacture, use and sale of its model 7210 cardioverter and lead model 6882 in mid-1983.

The model 7210 and its lead, an implantable unit, was intended to treat tachycardia.

Sixteen units of Medtronic's 7210 with the model 6882 lead were implanted in human beings in the United States.

Medtronic abandoned production of the model 7210 and has no plans to make, use or sell its model 7210 in the future.

Around June, 1987, Medtronic began the manufacture, use and sale of its Model 7215 cardioverter, a defibrillation device with its associated leads, model 6891, 6892, 6893 and 6917. Model 7215 is an automatic implantable defibrillator which also includes

a bradycardia pacemaker.

The Model 7215 is designed to treat bradycardia, ventricular tachycardia and ventricular fibrillation.

Medtronic has implanted four Model 7215 with their associated leads in human beings in Canada.

During the course of this litigation, on December 6, 1985, Medtronic initiated re-examination of the '757 patent and the '536 patent in the United States Patent and Trademark Office, which I will refer to as the PTO.

In my order of January 10, 1986, I stayed this present litigation, pending the outcome of the re-examination proceedings and ordered that the parties were to be bound by the ruling of the PTO on the specific issues decided by the PTO.

I further ordered that the parties would not be bound with respect to issues which the PTO is not empowered to decide on re-examination or which it in fact did not decide during the course of its re-examination.

The validity of the claim of the '757 patent in light of the prior art listed in the re-examination certificate was determined during the course of the re-examination proceedings, and Claims 1 to 3, 5 and 6 were allowed without change. Claim 4 was amended to include the phrase, "through electrodes, with electrical energy applied directly to the heart."

The validity of the claims of the '536 patent in light of the prior art listed in the re-examination certificate was determined during the re-examination proceedings, and Claim 1 was allowed without change.

During the re-examination, the PTO determined that the only disclosure of "implantability" in the '757 patent specification is "that at least one electrode is adapted to be positioned within the heart."

The PTO also decided that the claims of the '757 patent are not limited to the concept of a "totally implantable device."

Claim 1 of the '757 patent provides for a device for automatically cardioverting a malfunctioning heart. The device is

to be comprised of a means for continually sensing the function of a heart, with means for discriminating between normal and abnormal heart function, a means for storing electrical energy for cardioverting, an electrode means for connecting the storage means directly to the heart with at least one of the electrodes to be positioned within the heart, and a means for automatically switching the storage means into a discharge state in response to an abnormal condition indication from the discriminatory means, resulting in application of the stored electricity directly to the heart through the electrodes.

Claim 2 of the '757 patent provides a means for ensuring that a time delay exists between the sensing of the initial heart malfunction and the discharge of the electricity to the heart.

Claim 3 of the '757 patent provides for a means for inhibiting the discharge of the storage means under the conditions of normal heart activity.

Claim 4 of the '757 patent provides for the method of automatically sensing and cardioverting a malfunctioning heart. The method comprises a step of continually sensing the function of the heart, discriminating between normal and abnormal heart function, automatically starting a cycle for shocking the heart in response to the sensing of abnormal function, shocking the heart through electrodes, with electrical energy applied directly to the heart to cause cardioversion and inhibiting the shocking cycle under conditions of normal heart function.

Claim 5 provides for a device for automatically cardioverting a malfunctioning heart. The device is to be comprised of a means for continually sensing the function of the heart, with means for discriminating between normal and abnormal heart functions, a means for storing electrical energy for cardioverting, an electrode means for connecting the storage means into a discharge state whereby the stored energy is applied directly to the heart through the electrode means, a delay means for ensuring that a time delay exists between the sensing of the initial heart malfunction and the discharge of the storage means into the heart, and a means for inhibiting the discharge of the storage means whenever conditions of normal heart activity are sensed.

Claim 6 provides for the device as recited in Claim 5 where at least one of the electrode means is adapted to be positioned within the heart.

Claim 1 of the '536 patent provides for a method for cardioverting a malfunctioning heart with a single intravascular catheter carrying first and second spaced electrodes for delivering to the heart electrical energy to cardiovert the heart. The claim further provides a method comprising the steps of positioning the single intravascular catheter into association with the heart, with the first electrode located within the heart chamber to be cardioverted, and the second electrode located outside the heart chamber, sensing heart activity and delivering energy to the heart across the first and second electrodes when a malfunction susceptible to conversion by electrical shock is sensed.

During the re-examination of the '757 patent, the PTO considered 17 patents and 21 publications as prior art, including the Berkovits patent, Trial Exhibit 1304, the Satinsky article, Trial Exhibit 1164, and the Hopps article, Trial Exhibit 1172.

During the re-examination of the '536 patent, the PTO considered 11 patents and 13 publications as prior art, including the Hopps article.

All the elements of the invention patented in the '757 patent are not found in any single prior art patent, publication or device relied on by Medtronic.

All the elements of the invention patented in Claim 1 of the '536 patent are not found in any single prior art patent, publication or device relied on by Medtronic.

Trial Exhibit 1188, referred to as the Cotelec document, was disseminated or otherwise made available in a foreign country to persons of ordinary skill in the art of defibrillation prior to February 19, 1969.

The jury concluded, and I concur, that the Cotelec document was a printed publication in a foreign country prior to February 9, 1969.

The jury concluded, and I concur, that Medtronic failed to prove by clear and convincing evidence that every element of

Claim 4 of the '757 patent is found in the Cotelec document.

The Cotelec document illustrates an automatic defibrillator, a method of continually sensing the heart with a discriminatory means, a delay and inhibiting means and a means to cardiovert a malfunctioning heart.

The device described in the Cotelec document could deliver only one shock and then had to be manually restarted.

A physician had to be in attendance during the use of the Cotelec device.

The Cotelec publication does not describe a storage means for electrical energy.

The Cotelec publication contemplated use of AC current with the unit obtaining its current from a wall socket.

The Cotelec publication does not describe internal electrodes, but states that they should be applied to the cardiac muscle.

The Cotelec reference to internal electrodes was in the context of open-heart defibrillation.

The Berkovits patent, the Stephenson article, which is Trial Exhibit 1167, and the Satinsky article reveal storage means in a defibrillator.

The Satinsky article does not specify that electrodes must be placed directly on the heart or that energy is applied directly to the heart.

The Berkovits patent did not provide for the possibility of inhibition, but discloses applying a defibrillation shock directly to the heart to cause cardioversion.

The Iwa Moto article, Trial Exhibit 1227, discloses application of a defibrillation shock directly to the heart to cause cardioversion.

The Hopps cardioverter disclosed in the Hopps reference was not automatic, did not have a means for continually sensing the function of the heart, did not have a means for discriminating between normal and abnormal heart activity, and did not use an energy storage means.

The Hopps reference discloses internal positioning of electrodes.

The experiments in defibrillation conducted by Dr. Schuder during late 1969 and January and February of 1970, were not disclosed in a publication until June of 1970.

Dr. Schuder implanted a defibrillator in a dog on January 16, 1970.

The electrodes used in Dr. Schuder's defibrillator were applied on the external rib cage, and thus were separated from the heart.

All of the prior art references relied on by Medtronic at trial lack one or more of the elements of each of the claims in issue of the '757 and '536.

The patented invention as a whole was not taught by the prior art relied on by Medtronic.

A person of ordinary skill in the art is one who is knowledgeable in the field specified, who is familiar with the literature, and who understands the technical merits.

The application for the '757 patent was first filed on February 9, 1970, by Ronald Cohn, Dr. Mirowski's counsel. The application was later filed as a reissue application on February 25, 1972. And the '757 patent was issued on September 11, 1973.

The application for the '536 patent was originally filed by Medtronic counsel on behalf of Dr. Mirowski on March 15th, 1971, as patent application No. 124,326, which has been referred to as 326 application, but that was later abandoned. The application for the '536 patent was filed on September 19, 1973, by counsel for Dr. Mirowski as a continuation-in-part of the 326 application. The '536 patent was issued on March 9, 1976.

Medtronic decided to discontinue its defibrillation program and, in notices dated September 14, 1972, canceled its relationship with Dr. Mirowski and Dr. Morton Mower, a collaborator of Dr. Mirowski's.

By an instrument dated November 14, 1972, Medtronic assigned the patent rights under the '757 patent and the 326 applications back to Dr. Mirowski. Dr. Mirowski then executed

a power of attorney to his counsel, Ronald Cohn, Esquire, on November 20th, 1972. Mr. Cohn thereafter prosecuted the '757 and 326 applications on behalf of Drs. Mirowski and Mower.

Examiner Kamm handled the patent applications for both the '757 and '536 patents. He also conducted the re-examination of both patents in suit. These applications and re-examination proceedings were handled contemporaneously for both patents by Examiner Kamm.

On May 2nd, 1972, Examiner Kamm performed a prior art search in connection with the 326 application.

Examiner Kamm found the Hopps article and cited it in a letter of August 3rd, 1972, to Medtronic's counsel.

Medtronic had a copy of the Hopps reference in 1972 at the time of the prosecution of the '757 patent.

Medtronic's counsel failed to cite the Hopps article to Examiner Kamm during their prosecution of the '757 patent.

In letters of September 29th, 1972, and October 12th, 1972, to Ronald Cohn, Medtronic stated that its cancellation of the defibrillation program was based, in part, on its belief that the Hopps article invalidated the '757 patent because it disclosed the use of an electrode positioned within the heart for defibrillation.

On November 28th, 1972, Ronald Cohn filed a letter with the PTO with regard to the '757 application citing the Hopps reference and other articles and indicating that "none of these references is any more pertinent than those already cited in connection with the prosecution of this application."

Mr. Cohn did not submit a copy of the Hopps reference to Examiner Kamm in connection with the '757 patent application.

In his testimony, during the course of this litigation, Dr. Hopps stated that his article taught that larger dogs or larger hearts could not be defibrillated by the technique taught in his article.

Dr. Hopps himself concluded that shocks applied through an intracardiac catheter were not effective in cardiac defibrillation and that delivering large energies through a catheter dispersive electrode arrangement would not be successful for larger, that is human hearts.

Examiner Kamm had a copy of the Hopps reference during the re-examination of the '757 patent.

All the claims of the '757 patent were initially rejected during the re-examination on the basis of Hopps' teaching of direct application of cardioverting energy to the heart.

Dr. Mower was subsequently interviewed by Examiner Kamm. This was during the re-examination of the '757 patent and Dr. Mower at that time stated that some of the successful defibrillations reported by Hopps might have been the result of spontaneous defibrillation in small dogs.

Dr. Mower, in an affidavit to Examiner Kamm, stated that Hopps recognized a relationship between the size of the dog and the ability to close-chest defibrillate. Dr. Mower also stated that the Hopps experiments were totally unsuccessful with regard to larger dogs having heart sizes closer to that of human beings.

Dr. Mower did state to Examiner Kamm to the Hopps reference indicated that closed-chest defibrillation with a catheter electrode was possible in small dogs.

Dr. Mower did not disclose to Examiner Kamm his association with Dr. Mirowski or his interest in this litigation.

Dr. Mower testified at trial that he believed Examiner Kamm knew of his relationship with Dr. Mirowski because he and Dr. Mirowski were named as inventors of the '536 patent.

In his testimony at trial, Dr. Mower expressed his belief that small dogs occasionally spontaneously defibrillate. Dr. Mower's representations to Examiner Kamm were made on the basis of this belief which was a result of his own experience and that of other researchers.

In a 1974 publication, of which Dr. Mower was listed as one of the authors, there is a statement that spontaneous defibrillation never occurs in adult dogs, sheep or in man.

Dr. Mower did not reveal to Examiner Kamm his 1974

publication, the references upon which he based his belief that small dogs spontaneously defibrillate, or references which contradict that belief.

Both Mr. Cohn and Dr. Mower believed that the Hopps reference did not invalidate the '757 patent application.

At the time Mr. Cohn could reasonably have concluded that Examiner Kamm had a copy of the Hopps reference and was aware of it, since it was Examiner Kamm who first cited the reference to Medtronic's counsel in 1972 and the two patent applications and re-examinations were being processed by Examiner Kamm at the same time.

Neither Mr. Cohn nor Dr. Mower intended to withhold the Hopps reference from Examiner Kamm or to mislead him with regard to its teachings and the patentability of the '757 claim.

Dr. Mower's favor to disclose his relationship with Dr. Mirowski to Examiner Kamm during the re-examination of the '757 patent was the result of his good faith belief that Examiner Kamm knew of his collaboration with Dr. Mirowski on the '536 patent.

Dr. Mower's failure to reveal his interest in this litigation was an error in judgment, not result of any intent to deceive Examiner Kamm.

Dr. Mower was a credible witness at trial, entitled to belief, and, in fact, I did believe him.

During the re-examination of the '757 patent, Examiner Kamm relied on Dr. Mower's affidavit in concluding that the Hopps article should not be considered a clear teaching for catheter defibrillation and in confirming the claim of the '757 patent with one amendment to Claim 4.

The 326 patent application, filed March 15, 1971, discloses a single intravascular catheter electrode system with a suggested inter-electrode spacing of 4 to 4.5 inches when the catheter is used for ventricular defibrillation.

The 326 patent application indicates that the inter-electrode spacing of 4 to 4.5 inches is a "good average" and that the required

spacing of electrodes "will be slightly different from one patient to the next."

The 326 patent application also indicates that the intravascular catheter electrode system disclosed in the patent application can be used in an atrial electrode arrangement in addition to its use in treating ventricular tachycardia and fibrillation.

The second application for the '536 patent, which was filed on September 19th, 1973, as a continuation-in-part of the 326 application discloses a single intravascular electrode system with inter-electrode spacing of at least two and a half inches to three inches apart.

During the prosecution of the '536 patent application, Drs. Mirowski and Mower, through their counsel, Ronald Cohn, represented to the PTO that the space electrodes were defined in the claims of the patent application as "either being at least about two and one half inches apart, or adapted to reside in specific regions in such a manner which clearly defines an electrode spacing of on" – that's what it says – "the same order."

During the prosecution of the '536 patent application, Drs. Mirowski and Mower, through their counsel, Ronald Cohn, represented to the PTO that the inter-electrode spacing of the '536 patent application was not taught by any references of the record or any prior art.

The claims of the 536 patent disclose inter-electrode spacing of two and a half inches, three to five inches, four and four and a half inches and two and a half to four inches apart.

Drs. Mirowski and Mower published a certain article referred to as an abstract in April 1972 in a publication called Clinical Research. This abstract described a defibrillation system that uses a single intravascular catheter with two electrodes spaced by three and a half to 4.7 inches.

Neither Dr. Mower nor Dr. Mirowski disclosed a publication of the abstract to Examiner Kamm.

Dr. Mower testified at trial that the two and a half inch inter-electrode spacing in the '536 patent corresponded to the size of the right atrium and that such spacing in the catheter's use

in an atrial electrode arrangement was disclosed in the 326 patent application.

Dr. Mower testified at trial that he believed that a disclosure of inter-electrode spacing of two to two and a half inches was inherent in the September 19, 1971 application for the '536 patent.

Dr. Mower testified that he considered the abstract published in 1972 to have been published after the application for the '536 patent and the disclosure in that application of inter-electrode spacing.

During the prosecution of the '536 patent application, Drs. Mirowski and Mower disclosed to the PTO the Charms patent, Patent No. 3,738,370. The Charms reference was cited to Examiner Kamm as being "of interest only."

The Charms patent contains electrode spacing disclosures which are interchangeable with the spacing disclosures contained in the abstract published by Drs. Mirowski and Mower.

Medtronic submitted the withheld abstract to Examiner Kamm during the re-examination of the '536 patent.

Examiner Kamm determined that the abstract was "pertinent" to the claim limitations of inter-electrode spacing in the '536 patent, but based his rejection of certain claims on the Charms reference.

During the re-examination of the '536 patent, Examiner Kamm determined that, because of spacing claims of the '536 application were not described in the 326 application, the spacing claims of the '536 application were entitled only to the '536 application filing date rather than the 326 patent application filing date.

Neither Dr. Mirowski nor Dr. Mower withheld the abstract in an effort to mislead or deceive Examiner Kamm during the prosecution of the '536 patent. Indeed they revealed the existence of the Charms patented.

Prior to the invention disclosed in the '757 and '536, a number of persons skilled in the art of defibrillation were attempting to invent a defibrillator such as the patented invention.

The devices of the patents filled a long-felt need for such a treatment for ventricular tachycardia and ventricular fibrillation.

The development of its defibrillator under the '757 and '536 patents had been the reason for CPI's recent profitability and growth.

The success and acceptance of CPI's defibrillators has also improved sales of CPI's pacemakers.

The patented invention has been recognized in the medical field as a life-saving device.

Dr. Mirowski has been recognized as a pioneer in the field of defibrillation.

The '757 patent is a very basic patent entitled to broad protection.

I granted Lilly's motion for a directed verdict with regard to the validity of the '536 patent and the infringement of Claim 1 of the '536 patent by Medtronic's devices.

The jury decided model 7210 infringes Claims 1 through 6 of the '757 patent. I also conclude that model 7210 infringes these claims of the '757 patent.

The jury decided that Model 7215 infringes Claim 5 of the '757 patent. I also conclude that Model 7215 infringes Claim 5 of the '757 patent.

The jury decided that Medtronic's infringement of the patents in suit was willful, and I concur.

For purposes of Lilly's motion for an injunction, I find that model 7210 contains all the elements of Claim 1 of the '757 patent, including a means for continually sensing the function of the heart.

As commonly understood, the word "continually" means regularly and without any substantial interruption of sequence. It does not mean without interruption whatsoever.

Model 7210 contains the element of Claim 2 of the '757 patent in that it contains a delay means.

Model 7210 contains Claim 3 of the '757 patent in that it contains a means for inhibiting discharge of the storage means under conditions of normal heart activity. As commonly understood, the word "inhibit" means to restrain or old in check.

Model 7210 incorporates the elements of Claim 4 of the '757 patent in that it performs the method described in Claim 4.

Model 7210 contains the elements of Claim 5 of the '757 patent.

Model 7210 contains the elements of Claim 6 of the '757 patent in that the 7210 provides that at least one electrode is adapted to be positioned within the heart.

Model 7215 incorporates the elements of Claim 4 of the '757 patent in that when implanted, it performs a method described in Claim 4.

Model 7215, however, does not infringe Claim 4 since no implants of the 7215 were made in the United States.

Model 7215 contains the elements of Claim 5 of the '757 patent.

Model 7210 and 7215 perform substantially the same function as the patented invention in substantially the same way with substantially the same result as the patented invention.

Medtronic has planned to manufacture a 7216 which is similar to Model 7215, but can deliver a greater amount of electrical energy.

With its models 7210 and 7215, Medtronic plans to enter and eventually dominate the market for tachycardia and defibrillator devices in the United States. As I previously stated, Medtronic is an industry leader in the field of medical devices, including those that are used to treat heart problems.

The '757 patent was originally to expire on October 26, 1988, but a two-year extension was granted by the PTO pursuant to 35 United States Code, Section 156.

The '757 patent will, thus, expire on October 26, 1990.

The '536 patent will expire on September 19, 1993.

Lilly and CPI will be irreparably harmed if Medtronic is not enjoined from further infringement of Lilly's patents.

CPI has invested over $20 million in development of its devices under the patents-in-suit.

Denial of an injunction would allow Medtronic to use its defibrillation devices and its current strength in the pacemaker industry to dominate the market involving devices for treating tachycardia and fibrillation.

Future monetary damages could not adequately compensate Lilly for its right to exclude Medtronic under the patents.

While the public interest is unquestionably advanced through the marketing of potentially lifesaving devices such as Medtronic's, Congress has determined it better for the nation in the long run to afford the inventors of novel, useful and non-obvious products short-term exclusivity on such products rather than to permit free competition in the goods. Congress has not seen fit to differentiate between what might be referred to as lifesaving devices and those of a more trivial or less important nature.

The public interest is served by granting injunctions to effectuate patent rights.

Lilly and CPI are continuing the advanced development of their defibrillation devices and making such devices available to the public. There was no inequitable conduct attributable to the plaintiff.

I reach the following conclusions of law. Jurisdiction in this case is based on 28 United States Code, Section 1338.

Venue and personal jurisdiction are proper and are not contested, as stipulated by the parties. This Court has jurisdiction over the parties and subject matter of this suit.

Lilly has proved by a preponderance of the evidence that Medtronic's model 7210 infringes the '757 and '536 patents.

Lilly has proved by a preponderance of the evidence that Medtronic's Model 7215 infringes the '757 and '536 patents.

Lilly has proved by clear and convincing evidence, and the

jury has decided, that Medtronic's infringement of the '757 and '536 patents was willful.

On the basis of the prior art presented at trial, Medtronic has failed to prove by clear and convincing evidence that every single element of the invention claimed by the '757 patent is found in one single prior art patent, publication or device.

On the basis of the prior art presented at trial, Medtronic has failed to prove by clear and convincing evidence that every single element of the invention claimed by Claim 1 of the '536 patent is found in one single prior art patent, publication or device.

On the basis of the prior art presented at trial, Medtronic has failed to prove by clear and convincing evidence that the differences between the subject matter claimed and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art in question.

On the basis of the evidence presented at trial, Medtronic has failed to prove by clear and convincing evidence that each of the patents of Dr. Mirowski was procured by inequitable conduct before the PTO, such as to render the patents unenforceable.

On the basis of the evidence presented at trial, Medtronic has failed to prove by clear and convincing evidence that the description of the inventions of the '757 patent and Claim 1 of the '536 patent, and of the manner and process of making and using them, is such as to fail to enable a person with ordinary skill in the art to make and use the inventions.

A patent gives the owner or his licensee the right to exclude all others from the use, manufacture or sale of devices which infringe his patent.

Courts having jurisdiction over patent cases "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent on such terms as the Court deems reasonable."

During an extension of the term of a patent which claims a product, the rights derived from the patent are "limited to any

use approved for the approved product before the expiration of the term of the patent under the provisions of law under which the applicable regulatory review occurred."

During an extension of the term of a patent which claims a method of using a product, the rights derived from the patent are "limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provisions of law under which the applicable regulatory review occurred."

The last two references were to 35 United States Code, Sections 156(b)(1) and 156(b)(2).

35 United States Code section 156(b)(1) and 35 United States Code Section 156(b)(2) do not preclude the issuing of injunctive relief in this case since Medtronic is only enjoined from any uses for which Lilly's products and methods for using a product had been approved prior to the expiration of the original patent terms.

The grant or denial of an injunction is within the sound discretion of this Court and of course depend upon the facts in each case, and specifically, here on the facts in this case.

Although a district court has discretion as to whether to enter an injunction or not, the exercise of that discretion cannot be arbitrary.

The grant of an injunction in this case would not be arbitrary.

While the grant of injunctive authority under 35 United States Code, Section 2283 is clearly in discretionary terms, injunctive relief against an infringer is the norm in a patent case, since monetary damages are often inadequate for continued infringement.

While damages are awarded as compensation for past infringement, an injunction is designed to present future infringement of a patent.

The jury determined damages for infringement based upon an assumed license for the period 1983 to March of 1988. An injunction, therefore, is appropriate to enjoin any future unlicensed and infringing manufactures, uses or sales by Medtronic.

The fact that Medtronic has ceased production of model 7210 does not prevent issuance of an injunction against any further infringement.

Any continued manufacture, use or sale of Medtronic's 7210 and its associated leads would infringe the '757 and '536 patents.

Any continued manufacture, use or sale of Medtronic's 7215 and its associated leads would infringe the '757 and could infringe the '536 patent.

Development of Medtronic's model 7216, since it is similar in design and function to the 7215, would infringe the '757 patent.

And accordingly, I will issue an injunction order.

APPENDIX G

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

MEMORANDUM AND ORDER

DITTER, J. April 21, 1988

Plaintiff Eli Lilly and Company brought this suit against defendant Medtronic, Inc. alleging infringement by Medtronic of two United States patents, No. Re. 27,757, reexamined and issued as Bl Re. 27,757 (the 757 patent) and No. 3,942,536, reexamined and issued as Bl 3,942,536 (the 536 patent). At the close of Medtronic's case, with the agreement of the parties, I granted Lilly's motion for a directed verdict with regard to the validity of the 536 patent and its infringement by Medtronic's Model 7210 and its associated leads. The jury subsequently returned a verdict in favor of Lilly, having found Medtronic's devices to infringe the claims of the 757 patent. The jury also decided that Medtronic's infringement of the 757 and 536 patents was willful. The parties agreed to submit for my determination the issue as to whether the alleged inequitable conduct of the patents' inventors,[1] Dr. Michel Mirowski and Dr. Morton Mower, before the United States Patent and Trademark Office (PTO) during the prosecution and reexamination of the patents-in-suit renders both patents unenforceable. For the reasons which follow and based upon the findings of fact and conclusions of law made

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[1] Dr. Michel Mirowski is the inventor of the 757 patent. Dr. Mirowski, Dr. Morton Mower, and Rollin H. Denniston, a Medtronic engineer, are listed as the inventors of the 536 patent.

of record on April 15, 1988, I conclude that Medtronic has failed to prove by clear and convincing evidence that the patents-in-suit are unenforceable because of inequitable conduct on the part of their inventors. Since I find that both patents-in-suit are enforceable, I will direct that judgment be entered in favor of Lilly and against Medtronic in accordance with the jury's verdict.

Medtronic contends that Drs. Mirowski and Mower were guilty of certain instances of inequitable conduct with regard to each of the patents in suit. I will discuss each of Medtronic's claims.

A. The 757 Patent

1. Conduct During Initial Prosecution of the 757 Patent

Medtronic argues that, in 1972, during the prosecution of the 757 patent, Dr. Mirowski and his counsel, Ronald Cohn, Esq., were guilty of inequitable conduct because they failed to disclose as prior art to Examiner William E. Kamm, the patent examiner who was reviewing the 757 patent application,[2] an article published in 1954, by Dr. John Hopps. Medtronic contends that the Hopps article renders the 757 patent invalid because it specifically teaches the use of an electrode positioned within the heart for defibrillation, one of the features of the claims of the 757 patent.

The patent application for the 757 patent was first filed on February 9, 1970, by Ronald Cohn, Dr. Mirowski's counsel. Medtronic counsel later assumed the prosecution of the 757 patent on behalf of Dr. Mirowski. A reissue application for the 757 patent was filed on February 25, 1972. The application for the 536 patent was filed by Medtronic counsel on behalf of Dr. Mirowski on March 15, 1971, as patent application Serial No. 124,326 (the 326 application). At the time, Medtronic was undertaking prosecution of both Dr. Mirowski's patent applications under an agreement with Dr. Mirowski to develop the invention of the 757 patent application, an automatic defibrillator. Medtronic

[2] Examiner Kamm handled both the application for the 757 patent and the application for the 536 patent. He also reexamined both the patents-in-suit.

subsequently decided to discontinue its defibrillation program and its relationship with Dr. Mirowski and assigned the patent rights under the applications back to Dr. Mirowski. Dr. Mirowski's counsel, Mr. Cohn, thereupon undertook prosecution of the patent applications on behalf of Dr. Mirowski.

On May 2, 1972, Examiner Kamm performed a prior art search in connection with the 326 application and found the Hopps article which he cited to Medtronic counsel in a letter of August 3, 1972. Sometime prior to August 7, 1972, however, Medtronic had a copy of the Hopps reference in its corporate library, although Medtronic disputes whether the Medtronic counsel prosecuting the 757 patent were aware of it. In any event, after being informed of the Hopps article by Examiner Kamm with regard to the 326 application, Medtronic failed to cite the article to Kamm with regard to the 757 patent application despite its responsibility under the agreement with Dr. Mirowski for prosecution of the 757 application. Having cancelled its relationship with Dr. Mirowski by a notice dated September 14, 1972, Medtronic, in letters of September 29, 1972, and October 12, 1972, to Mr. Cohn stated that its cancellation of its defibrillation program was based, in part, on its belief that the Hopps article invalidated the 757 patent because it disclosed the use of an electrode positioned within the heart for defibrillation.[3]

After Medtronic assigned the patent rights back to Dr.

[3] The September 29, 1972, letter states:

> We have reviewed the defibrillator program and as indicated in our cancellation notices dated September 14, 1971 (sic) to Drs. Mirowski and Mower, we have decided to discontinue the program. *Therefore*, we have undertaken and completed a comprehensive study of the issued patents and pending applications involved in the program.

Trial Exhibit 269 (emphasis added). Lilly argues that the inference from the timing of the letters and the language of the September 29, 1972, letter is that Medtronic decided to cancel its defibrillator program and relationship with Drs. Mirowski and Mower and *then* decided to use the Hopps reference as justification for doing so. Medtronic contends that the Hopps reference was "The straw that broke the camel's back," leading to cancellation of Medtronic's relationship with both doctors. Trial Transcript, Testimony of Donald Stone, Day 8, p. 153).

Mirowski in an assignment dated November 14, 1972, Dr. Mirowski executed a power of attorney to Ronald Cohn on November 20, 1972. Mr. Cohn thereupon prosecuted the 757 and 326 applications on behalf of Drs. Mirowski and Mower. In a letter of November 28, 1972, to Examiner Kamm regarding the 757 application, Mr. Cohn cited the Hopps reference and other articles saying that "none of these references is any more pertinent than those already cited in connection with the prosecution of this application." Mr. Cohn did not submit a copy of the Hopps reference to Examiner Kamm.

2. Conduct During the Reexamination of the 757 Patent

Medtronic alleges certain statements made by Dr. Mower during the reexamination of the 757 patent with regard to the teachings of the Hopps article and the possibility of spontaneous defibrillation in small dogs constituted inequitable conduct. Medtronic also alleges that Dr. Mower intentionally withheld certain publications which contradict his statements to Examiner Kamm about spontaneous defibrillation in small dogs and the success of the Hopps experiments. Finally, Medtronic alleges that Dr. Mower intentionally withheld from Examiner Kamm the fact of his professional relationship with Dr. Mirowski.

During the reexamination of the 757 and 536 patents initiated by Medtronic in connection with this litigation, Medtronic submitted a copy of the Hopps reference to Examiner Kamm. All of the claims of the 757 patent were initially rejected by Examiner Kamm on the basis of Hopps teaching of direct application of cardioverting energy to the heart.[4] As part of the reexamination proceedings, Dr. Mower was interviewed by Examiner Kamm and submitted an affidavit concerning the Hopps article.

The Hopps reference discloses the findings of Dr. Hopps' attempts in 1954 to defibrillate a number of dogs. In the portion

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[4] Lilly contends, and the testimony of Medtronic's expert, Professor Samuel Sutton, supports the fact that claims of patents are routinely, initially rejected in reexamination only to be later allowed without modification.

of the reference entitled "Closed Chest Defibrillation", the first attempt discussed involved a "modification of the intracardiac catheter electrodes as they lay in various portions in the right atrium and right ventricle." Trial Exhibit 1172, p. 841. As the article explains,

> "[i]n every case but one, fibrillation persisted about the apex, and it was impossible to reach this extremity of the ventricles with the shock. In each instance, there was an area of burnt tissue around the electrodes after three or four shock applications. The one exception was a ten-kilogram dog whose heart was defibrillated on the fifth attempt . . ."

Id. The ten-kilogram dog was one of the smallest dogs in Hopps' experiment. *Id.*

In Dr. Hopps' next experiment, "a single electrode catheter in the heart and a large dispersive electrode on the front of the chest, over the apex of the heart" was used. *Id.* at 841-43. As explained in the article, "the technique proved fairly satisfactory in five of the eleven dogs." *Id.* at 843. Two of the five successes, however, were discounted because "the first attempts to defibrillate were unsuccessful, and it was necessary to open the chest, massage, and defibrillate with conventional electrodes before performing further tests with atrium-chest electrodes. Subsequent defibrillations by this method did not constitute valid tests under closed chest conditions." *Id.* Thus, closed chest defibrillation was successful in only 3 of 11 dogs. Dr. Hopps' report concluded:

> 5. Shocks applied through an intracardiac catheter were not effective in cardiac defibrillation. It was impossible to arrest the ventricular muscle around the apex by this method.
>
> 6. With a single intracardiac electrode and a dispersive electrode on the chest over the heart, closed-chest defibrillation was possible in smaller dogs. As in open-chest technique, there appears to be a relationship between the size of the dog and the ability to defibrillate.

Id.

Dr. Mower's affidavit to Examiner Kamm stated that the first closed chest technique was a failure and discussed this technique. Trial Exhibit 1173, para. 5-6. Dr. Mower noted that the second technique was reported as "fairly satisfactory" in five of the eleven dogs that were tested. *Id.* at para. 8. Dr. Mower explained that two of the five successes were discounted by Hopps and, thus, that "only three of the eleven dogs were apparently defibrillated in the manner intended." *Id.* at para. 7-8. Dr. Mower then noted that the three dogs that were defibrillated had weights lower than those dogs that could not be defibrillated. *Id.* at para. 9. Dr. Mower indicated in his affidavit that Hopps himself reached a similar conclusion that "there appeared to be a definite relationship between the size of the dog and our ability to defibrillate . . . [w]ith a larger dog, the greater the size of heart and increased current path undoubtedly contribute to the difficulty of defibrillation." *Id.* at para. 9.

Dr. Mower concluded his affidavit to Examiner Kamm by explaining that the Hopps reference would teach a person of ordinary skill in the art "that delivering large energies through a catheter/dispersive electrode arrangement would not be successful for larger hearts, such as human hearts." *Id.* at para. 13. Dr. Mower explained his conclusion by stating, "I believe that Hopps et al recognized this when they concluded, at page 848, that closed-chest defibrillation with a catheter electrode and dispersive electrode was possible in smaller dogs, in view of their further conclusion that there appears to be a relationship between the size of the dog and the ability to defibrillate (sic) (p. 848)." *Id.* Dr. Mower further concluded in his affidavit that "[t]he Hopps et al experiments were totally unsuccessful for larger dogs having heart sizes that would be closer to the size of a human heart. As such, one would be convinced by the Hopps et al teaching that the human heart would similarly be unsuccessfully treated." *Id.*

In his affidavit, Dr. Mower also stated that the dogs that Hopps reported as "successes" might have spontaneously defibrillated. Dr. Mower explained:

> "[I]t is possible that the dogs may have spontaneously defibrillated . . . It is well known that smaller animals frequently spontaneously defibrillate. Hopps et al themselves state, at page 840, that "[i]n human beings, as in most of the larger animals, it [fibrillation] is usually not reversible spontaneously," thus implying what is generally known, i.e., that small animals can defibrillate spontaneously. Thus, I cannot be certain that the return to normal heart rhythm of the three small dogs resulted from the energy that was applied via the catheter dispersive electrode arrangement, and not the phenomenon of spontaneous defibrillation."

Id. at para. 11.

In his trial testimony, Dr. Hopps testified that his article taught those of ordinary skill in the art that larger dogs or larger hearts could *not* be defibrillated by the method discussed in his article. Trial Transcript, Testimony of Dr. John Hopps, Day 10, p. 160 (emphasis added). Dr. Mower, in his testimony at trial, maintained his belief that small dogs occasionally spontaneously defibrillate and that spontaneous defibrillation might have been the reason for the successes reported in the 3 dogs that were defibrillated. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, p. 68, P. 72, p. 112-14.

Medtronic further contends that Dr. Mower intentionally withheld from Examiner Kamm a 1974 publication of his which purportedly contradicts his statements to Examiner Kamm regarding spontaneous defibrillation.[5] Dr. Mower's publication confirms that ventricular fibrillation can be spontaneously reversed in small animals such as frogs, turtles, and cats. The article, however, also includes a statement to the effect that spontaneous defibrillation "has never been observed in over 200

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[5] Medtronic also contends that Dr. Mower should have disclosed certain other publications including the Wiggers and Garrey references. The Wiggers reference states that, in the hearts of larger animals, fibrillation is irrevocable and notes that in over 400 cases of fibrillation in dogs, only a single recovery was witnessed. Trial Exhibit 1406, p. 399. The Garrey reference states that the ventricles of dogs do not usually recover spontaneously from fibrillation, although they do so in rare instances. Trial Exhibit 1174, p. 397

dogs of the body weight range described in the present experiments."[6] Trial Exhibit 1178, p. 860. At trial, Dr. Mower explained that the statement was "the experience of two of our coauthors. It certainly wasn't my own experience. I had seen spontaneous defibrillation many times and the literature amply supported the fact that it occurs." Trial Transcript, Testimony of Dr. Morton Mower, Day 11, p. 72.

To sustain the defense of inequitable conduct, Medtronic must prove two things by clear and convincing evidence: 1) that Drs. Mirowski or Mower or their counsel misrepresented or failed to disclose material information to the PTO in the prosecution and reexamination of the patents-in-suit, and 2) that such misrepresentation or omission was intentional or the result of gross negligence. *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1094 (Fed. Cir. 1987). *See also FMC Corp v. The Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed.Cir. 1987) (one who alleges failure to disclose as inequitable conduct must offer clear and convincing proof of: 1) prior art or information that is material; 2) knowledge by the applicant of the materiality of the prior art or information; and 3) failure to disclose resulting from an intent to mislead the PTO).

The United States Court of Appeals for the Federal Circuit has stated that a trial court, in determining a claim of inequitable conduct, must balance the materiality of any withheld reference with the level of intent with which the prior art was withheld from the PTO. *FMC Corp.*, 835 F.2d at 1415; *Laitram Corp. v. Cambridge Wire Cloth Co.*, 785 F.2d 292, 294 (Fed. Cir. 1986); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir.), *cert. denied*, 469 U.S. 821 (1984). Having reviewed all the evidence with regard to Medtronic's specific allegations of inequitable conduct on the part of Dr. Mirowski and his counsel during the prosecution of the 757 patent, I can only conclude that Medtronic has failed to prove by clear and convincing evidence that Dr. Mirowski or his counsel was guilty

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[6] The dogs to which the 1974 article refers weighed 12-25 kilograms. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, p. 74. The dogs in the Hopps experiments weighed 10-22 kilograms. Trial Exhibit 1172, p. 843.

of any intentional or even grossly negligent withholding of any material information before the PTO.

First, the materiality of the Hopps article as a prior art reference is marginal at best. While the Hopps reference does disclose the use of an electrode positioned within the heart for defibrillation, the results of Dr. Hopps' experiments concluded that shocks applied through an intracardiac catheter were not effective in cardiac defibrillation and that delivering large energies through a catheter dispersive electrode arrangement would not be successful for larger, human hearts. In his testimony at trial, Dr. Hopps himself admitted that this was the conclusion of his experiments and the teaching of his reference. The few successes which Hopps achieved were with the smaller of the dogs involved in the experiments. If anything, the Hopps article teaches that one could not successfully defibrillate a heart the size of a human heart through the techniques disclosed in the reference. The failure of Medtronic counsel to cite the Hopps article to Examiner Kamm while they were prosecuting the 757 patent on behalf of Dr. Mirowski suggests that, at the time, Medtronic counsel, too, thought the article of little relevance. It certainly cannot be concluded that Examiner Kamm would have considered the Hopps reference important in deciding whether to allow the 757 patent application or that, but for the Hopps reference, he would not have allowed the patent to issue. *See, e.g., J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2 1553, 1559 (Fed. Cir. 1984) (setting forth standards in determining materiality of nondisclosed information). Contrary to Medtronic's contention, moreover, the fact that the claims of the 757 patent were initially rejected on the basis of Hopps during the reexamination of the 757 patent does not establish the materiality of the reference given the fact that all the claims were eventually allowed over the reference.

Even if there was some marginal materiality to the Hopps reference, Medtronic has made no showing that the failure of Dr. Mirowski or his counsel to provide a copy of the reference to Examiner Kamm was the result of an intent to mislead or deceive the PTO. *See, e.g., Akzo v. E.I. duPont deNemours & Co.*, 810 F.2d 1148, 1152 (Fed. Cir. 1987). At the time Dr. Mirowski's counsel, Mr. Cohn, cited Hopps to Examiner Kamm, he stated

that it was no more pertinent than any other references previously cited to the PTO. Medtronic has produced no evidence showing that Mr. Cohn and Dr. Mirowski did not believe this to be the case at the time they made such a representation to the PTO. Medtronic has not shown that the failure to provide a copy of the Hopps article to Examiner Kamm was anything other than the result of Dr. Mirowski's and Mr. Cohn's good-faith belief that the reference was irrelevant to the 757 patent application. *See, e.g., Allen Archery, Inc.*, 819 F.2d at 1095 (failure to cite competitor's patent as prior art did not constitute inequitable conduct where applicant had good-faith belief that competitor's patent was not material to the prosecution of applicant's patent). Such a belief, moreover, given the testimony at trial, has been shown to be a reasonable one. *See, e.g., Argus Chemical Corp. v. Fibre Glass-Evercoat Co., Inc.*, 759 F.2d 10, 14-15 (Fed. Cir. 1985) (subjective good faith of counsel in not disclosing prior art does not negate inequitable conduct). *See also Laitram Corp.*, 785 F.2d at 294 (*Argus* did not hold that subjective good faith is never a defense to a claim of inequitable conduct; rather, materiality and intent must be balanced). It was, further, not unreasonable for Dr. Mirowski or Mr. Cohn to conclude that Examiner Kamm had a copy of the Hopps reference since it was Kamm who first cited the reference to Medtronic counsel in 1972. I conclude that the Hopps reference was not material, that neither Dr. Mirowski nor his counsel intentionally or negligently withheld the reference, and that their failure to provide a copy of Hopps to Examiner Kamm during the initial prosecution of the 757 patent did not amount to inequitable conduct.

Medtronic has also failed to sustain its burden with regard to its allegations of inequitable conduct on the part of Dr. Mower during the reexamination of the 757 patent. Medtronic has not shown how Dr. Mower's statements to Examiner Kamm intentionally mislead, or misrepresented, or withheld material information regarding the Hopps reference. Dr. Mower's affidavit to Examiner Kamm accurately reflected the success and failure of the Hopps experiments and indicated that Hopps had recognized a relationship between the size of the dog and the ability to defibrillate, with the difficulty increasing with the size of the dog. Dr. Mower represented to Examiner Kamm that Hopps did

not teach the successful application of defibrillating energy to larger, human hearts, a conclusion which Hopps himself confirmed at trial.

Medtronic's most strenuous contention, however, has been its claim that Dr. Mower intentionally misrepresented to Examiner Kamm the likelihood that some of the Hopps successes could be attributed to spontaneous defibrillation in small dogs. Dr. Mower stated in his affidavit that he could not be certain that the successes achieved by Hopps were not the result of spontaneous defibrillation. As he explained at trial, Dr. Mower suggested this possibility because he believed spontaneous defibrillation in small animals to be a frequent occurrence. I find no intent on Dr. Mower's part to mislead Examiner Kamm by failing to provide his 1974 article or the Wiggers or Garrey references which contradict his position on spontaneous defibrillation. As Dr. Mower testified at trial, he believed other literature, to which specific reference was made, fully supported his opinion that small animals can spontaneously defibrillate. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, pp. 112, 124- 129.

Finally, Medtronic contends that Dr. Mower intentionally failed to disclose to Examiner Kamm his relationship with Dr. Mirowski. Medtronic argues that, because Dr. Mower has an agreement with Dr. Mirowski whereby Dr. Mower will receive a percentage of any recovery in this litigation, Dr. Mower should have disclosed this potential conflict to Examiner Kamm during the reexamination. At trial, Dr. Mower stated that he believed Examiner Kamm was aware of his close collaboration with Dr. Mirowski because both doctors were listed as inventors on the 536 patent and Examiner Kamm was handling both the 757 and 536 reexaminations.

I can find no inequitable conduct on the part of Dr. Mower in failing to disclose to Examiner Kamm his working relationship with Dr. Mirowski and his interest in this litigation. Dr. Mower testified that he believed Examiner Kamm knew of his association with Dr. Mirowski since both were listed as inventors of the 536 patent. This is a reasonable conclusion, moreover, since Examiner Kamm had handled both applications for the patents-in-suit as well as their reexamination. While Dr. Mower's interest in this litigation might have been of some relevance to Examiner Kamm

in evaluating Dr. Mower's statements during the reexamination, Dr. Mower's failure to disclose it is, at the most, an error of judgment which falls short of inequitable conduct. *See, e.g., Akzo*, 810 F.2d at 1152 (simple negligence or an error in judgment is never sufficient for a holding of inequitable conduct). An applicant need not disclose all information of pertinence to the PTO. The two controlling factors in determining a charge of inequitable conduct are the materiality of the withheld information and the intent of the actor. *Kimberly-Clark Corp. v. Johnson & Johnson Co.*, 745 F.2d 1437, 1454-55 (Fed. Cir. 1984) (citing *American Hoist*, 725 F.2d at 1362-64). Inequitable conduct is not established upon a showing that information of some materiality was not disclosed to the PTO. Rather, one must have intended to act inequitably. *FMC Corp.*, 835 F.2d at 1415. I cannot conclude, on the basis of the evidence presented at trial, that Dr. Mower had any such intent in not informing Examiner Kamm of his interest in this litigation.

B. **The 536 Patent**

With regard to the 536 patent, Medtronic alleges that the failure of Dr. Mower to disclose as prior art an article published by Drs. Mirowski and Mower in 1972 was inequitable conduct.

The 326 patent application, filed March 15, 1971, discloses a single intravascular catheter electrode system with a suggested inter-electrode spacing of 4 to 4 1/2 inches when the catheter is used for ventricular defibrillation. Trial Exhibit 733, p. 16. The second application for the 536 patent, which was filed on September 19, 1973, as a continuation in part of the 326 application, discloses a single intravascular electrode system with inter-electrode spacing of at least 2 1/2 to 3 inches. Trial Exhibit 628, p. 14. The claims of the 536 patent also disclose inter-electrode spacing ranging from 2 1/2 inches to 4 1/2 inches.

During the prosecution of the 536 patent application, in 1973, Drs. Mirowski and Mower represented to the PTO that the inter-electrode spacing of the 536 patent application was not taught by any references of record or any prior art. In April, 1972, Drs. Mirowski and Mower published a certain abstract in *Clinical Research* detailing a defibrillation system that uses a single intravascular catheter with two electrodes spaced by 3.5 to 4.7

inches. Trial Exhibit 1144. Medtronic contends that this abstract discloses a catheter system with electrode spacing within the claimed ranges of the 536 patent application. Medtronic thus argues that the 1972 abstract, having been published before the filing of the 536 patent application in 1973, is prior art which should have been disclosed to the PTO by Drs. Mirowski or Mower in the course of the prosecution of the 536 application.

The 326 patent application indicates that inter-electrode spacing of 4 to 4.5 inches is a "good average" and that the required spacing of the electrodes "will be slightly different from one patient to the next." Trial Exhibit 733, p. 16. The 326 application also indicates that the catheter electrode system disclosed in the patent application could be used in an atrial electrode arrangement in addition to its use in treating ventricular tachycardia and fibrillation. *Id.* at 9.

During the reexamination of the 536 patent, many of the new spacing claims of the patent were rejected as obvious in view of the Charms patent, Trial Exhibit 1319. This patent, which was cited to Examiner Kamm by Drs. Mirowski and Mower as "of interest only" during the prosecution of the 326 application, has a disclosure of spacing ranges interchangeable with those disclosed in the 1972 abstract. Examiner Kamm determined that, because the 1972 abstract recited spacing ranges not described in the 326 application, the spacing claims of the 536 patent were entitled only to the 536 patent continuation-in-part filing date of September 19, 1973, rather than the 326 application filing date of March 15, 1971.

Dr. Mower testified at trial that the 2 1/2 inch inter-electrode spacing in the 536 patent corresponded to the size of the right atrium and that such spacing in the catheter's use in an atrial electrode arrangement was disclosed in the 326 patent application. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, pp. 100-101. Dr. Mower further testified that he believed a disclosure of inter-electrode spacing of 2 to 2 1/2 inches was inherent in the September 19, 1971, application for the 326 patent. *Id.* Finally, Dr. Mower also testified that he considered the abstract published in 1972 to have been published *after* the application for the 326 patent and the disclosure in that application of inter-electrode spacing. *Id.*

Given Examiner Kamm's findings during the reexamination regarding the spacing claims of the 536 patent, the materiality of the 1972 abstract is confirmed. Such a conclusion, however, does not establish that Dr. Mower was guilty of inequitable conduct in failing to cite the 1972 abstract to the PTO during the prosecution of the 536 patent. Medtronic has not shown by clear and convincing evidence that Dr. Mower intentionally concealed the abstract from Examiner Kamm or otherwise intentionally misled him with regard to the patentability of the spacing ranges claimed in 536 patent. Dr. Mower's trial testimony explained his belief that the 2 1/2 inch spacing range in the 536 patent was inherent in the 326 application and that the 1972 abstract was published after the filing date of the 326 application and was, thus, not prior art as to the 536 continuation-in-part application. Dr. Mower's failure to disclose the abstract, moreover, is made less significant given the fact that the Charms patent was cited by the inventors to Examiner Kamm during the prosecution of the 536 application. Even though it was cited as "of interest only", Charms, nonetheless, contains spacing claims identical to those in the abstract. Had Dr. Mower intended to conceal the spacing claims disclosed in the abstract, he certainly would not have disclosed the equally damaging Charms patent to Examiner Kamm. Balancing the materiality of the abstract against the lack of any showing by Medtronic of intent or gross negligence on the part of Dr. Mower, I must conclude that he is not guilty of any inequitable conduct before the PTO. *See, e.g., Akzo*, 810 F.2d at 1153 (although material misrepresentation was made to the PTO, patentee was not guilty of inequitable conduct where no showing was made of intent or gross negligence on the part of patentee). The 536 patent is, therefore, enforceable.

An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

ORDER

AND NOW, this 2lst day of April, 1988, for the reasons stated in the accompanying memorandum, it is hereby ordered:

1. United States patents, No. Re. 27,757, reexamined and issued as Bl Re. 27,757, and No. 3,942,536, reexamined and issued as Bl 3,942,536, are valid and enforceable;

2. Judgment is hereby entered in favor of plaintiff Eli Lilly and Co. and against defendant Medtronic, Inc., in the amount of $26,500,000, plus an additional royalty of $166,000, totaling $26,666,000.

BY THE COURT:

/S/ J. William Ditter, Jr.

APPENDIX H

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

ON MOTION

Before NEWMAN, BISSELL and MAYER, *Circuit Judges.*
NEWMAN, *Circuit Judge.*

O R D E R

Medtronic, Inc. (Medtronic) moves for a stay pending appeal of a permanent injunction entered by the United States District Court for the Eastern District of Pennsylvania. Eli Lilly and Company (Lilly) opposes the motion.

Lilly brought suit against Medtronic alleging infringement of two of Lilly's patents related to medical devices for automatically cardioverting or defibrillating potentially fatal abnormal heart rhythms. Judgment was entered in favor of Lilly on April 21, 1988. A separate order was entered on that day permanently enjoining Medtronic from manufacturing, using, or selling certain of its medical devices. The district court thereafter denied Medtronic's motion for a stay pending appeal on May 4, 1988. On June 6, 1988, Medtronic filed the instant motion for stay pending appeal.

Medtronic argues (1) that the appeal involves a substantial legal question of first impression, *i.e.*, whether the infringement exemption of 35 U.S.C. § 271(e)(1)* applies to medical devices, (2) that the public will be harmed if Medtronic's devices are not available, (3) that Lilly will not be harmed and, in any event, could be compensated through a reasonable royalty, and (4) that Medtronic will be harmed if clinical testing and Federal Drug Administration marketing approval are postponed.

Having reviewed Medtronic's motion and Lilly's opposition, we are not persuaded that Medtronic's motion should be granted. The district court firmly rejected Medtronic's legal argument and held that § 271(e)(1) applied only to drugs and not to medical devices. Medtronic alleges no other basis for likelihood of success on the merits. Further, Medtronic's allegations of harm, all challenged by Lilly, do not persuade us that the balance tips in Medtronic's favor.

Accordingly,

IT IS ORDERED THAT:

Medtronic's motion for stay pending appeal is denied.

FOR THE COURT

7/28/88
Date

/S/ P. Newman
Pauline Newman
Circuit Judge

cc: Philip S. Johnson, Esquire
Timothy J. Malloy, Esquire

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* Section 271(e)(1) of 35 U.S.C. provides:

It shall not be an act of infringement to make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

APPENDIX I

S 2860 March 16, 1989

CONGRESSIONAL RECORD -- SENATE

BY MR. DECONCINI:

S.622. A bill to amend title 35 of the United States Code to clarify the Drug Price Competition and Patent Term Restoration Act of 1984 with respect to medical devices, to promote increase competition and innovation in lifesaving medical technologies and to improve patient and physician access to advanced experimental therapeutical alternatives; to the Committee on the Judiciary.

MEDICAL TECHNOLOGY COMPETITTIVENESS ACT

MR. DECONCINI. Mr. President, I rise today along with my colleagues Senators DURENBERGER, ADAMS, and GORTON to introduce the Medical Technology Competition Act of 1989. This bill clarifies the Drug Price Competition and Patent Term Restoration Act of 1984 with respect to medical devices; it promotes increased competition and innovation in life-saving medical technologies; and it improves the access of physicians and patients to advanced experimental therapeutical alternatives.

My bill addresses what has become a point of some controversy with Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984. This law authorized the extension of certain patents in order to restore the patent time lost due to the period of FDA regulatory review for the patented inventions; and it also provided an experimental use or research exemption from infringement under which competitors can test experimental products. That is, the law permits competitors to engage in non-commercial research and development during the term of a patent so that commercial competition can proceed as soon as the patent expires. The law reversed the holding of *Roche Products v. Bolar Pharmaceutical Co.*, 221 U.S.P.Q. 937 (1984) by means of 35 U.S.C. 271(e)(1), which provides

> It shall not be an act of infringement to make, use, or sell a patent invention (other than a new animal drug or veterinary biological product) * * * solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs.

The 1984 law was explicit with respect to human drug products and, with the enactment of Public Law 100-670, is now explicit with respect to animal drug products. The law is not explicit with respect to medical devices and this must be clarified. The American Bar Association Section of Patent, Trademark and Copyright Law stated in its 1988 committee report:

> In summary, the [ABA] subcommittee wishes to state its conviction that such an experimental or research exemption either does exist or should exist. Such a research exemption should apply to all products, not just to generic drugs.

My bill provides the necessary statutory clarification for medical devices and reaffirms the purpose behind the 1984 law–to balance the rights of patent holders–who were provided with the ability to secure patent extensions–with the public good of immediate increased competition once the patent expires.

Even more alarming than the evident legal unfairness with the state of the law at this point is its apparent effect of prohibiting physicians from conducting clinical evaluations of state-of-the-art experimental medical devices that are desperately needed to treat serious heart conditions. A number of well- respected physicians at this country's leading hospitals and medical institutions have told me of seriously ill patients in need of an experimental medical device that cannot be used because it infringes the patent of a device already on the market. These physicians are, in effect, being blocked from practicing medicine to the best of their ability. The patients are immediate losers in this situation. We should also realize that, to a degree, we all are losers–because technological innovation is hampered, because medical progress is slowed, and because free competition and the ability to experiment are obstructed.

It is not often that one has the opportunity to take an action that will have as great an impact on patients' lives as will the

passage of this bill. I am mindful of the rights of patent holders, and I value the need to protect intellectual property rights. This bill will not change the term of the patent. However, it will ensure that there is not a de facto extension which occurs when competitors are forced to wait until after the patent expires before even beginning the experimental use required for FDA approval.

While this issue came to my attention as a result of a current legal controversy, my motivation in introducing this bill is not to side with one patent holder over another, and it is not to choose one course of medical treatment or medical device over another. My purpose is to restore the proper balance in our patent laws and to do it as quickly as possible in light of the immediate patient care situation. I am pleased that several of my colleagues upon learning of the importance of this issue have joined me in sponsoring this legislation and I urge my other colleagues to support this much-needed legislation. Mr. President, I ask unanimous consent that the bill be printed in the RECORD following my statement.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S.622

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Technology Competitiveness Act of 1989".

SEC. 2 INFRINGEMENT OF PATENT.

Section 271(e) of title 35, United States Code, is amended

(1) in paragraph (1) by inserting ", medical devices" before "or veterinary biological products";

(2) in paragraph (2) by –

(A) striking out "or" at the end of subparagraph (A);

(B) adding "or" at the end of subparagraph (B);

(C) inserting between subparagraph (B) and the matter that follows such subparagraph, the following:

"(C) an application under section 515(c) of such Act (21 U.S.C. 360e(c)) for a medical device which is claimed in a patent or the use of which is claimed in a patent,"; and

(D) inserting ", medical device" before "or veterinary biological products"; and

(3) in paragraph (4) by inserting ", medical device" before "or veterinary biological product" each place it appears in subparagraphs (A), (B), and (C).

APPENDIX J

STATUTE INVOLVED

35 U.S.C. § 271(e)

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit–

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under Section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)–

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285. (Added September 24, 1984, Public Law 98-417, sec. 202, 98 Stat. 1603; Amended November 16, 1988, Public Law 100-670, sec. 201, 102 Stat. 3989.)